

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON AT SPOKANE

CITY OF SPOKANE,

Plaintiff,

No. 2:19-cv-00381

v.

COMPLAINT

JURY DEMAND

ENDO HEALTH SOLUTIONS INC.; ENDO  
PHARMACEUTICALS, INC.; JANSSEN  
PHARMACEUTICALS, INC.; JOHNSON &  
JOHNSON; TEVA PHARMACEUTICALS  
INDUSTRIES, LTD.; TEVA  
PHARMACEUTICALS USA, INC.;  
CEPHALON, INC.; ALLERGAN PLC f/k/a  
ACTAVIS PLC; ALLERGAN FINANCE, LLC  
f/k/a ACTAVIS, INC. f/k/a WATSON  
PHARMACEUTICALS, INC.; WATSON  
LABORATORIES, INC.; ACTAVIS LLC;  
ACTAVIS PHARMA, INC. f/k/a WATSON  
PHARMA, INC; MALLINCKRODT PLC;  
MALLINCKRODT, LLC; SPECGX LLC; PAR  
PHARMACEUTICAL COMPANIES, INC.;  
PAR PHARMACEUTICAL, INC.; WEST-  
WARD PHARMACEUTICAL CORP.;  
HIKMA PHARMACEUTICALS PLC;  
MYLAN PHARMACEUTICALS, INC.;  
CARDINAL HEALTH, INC.; MCKESSON  
CORPORATION; AMERISOURCEBERGEN  
DRUG CORPORATION; WALGREENS  
BOOTS ALLIANCE INC. a/k/a WALGREEN  
CO.; THRIFTY PAYLESS, INC.; OMNICARE  
DISTRIBUTION CENTER LLC; OMNICARE,  
INC.; CVS HEALTH CORPORATION; CVS

COMPLAINT  
(2:19-cv-00381)

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1 PHARMACY INC.; CVS RX SERVICES,  
2 INC.; and JOHN AND JANE DOES 1  
3 THROUGH 100, INCLUSIVE,  
4 Defendants.

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## I. INTRODUCTION

1  
2 1. The United States is experiencing the worst human-made epidemic in modern  
3 medical history—the misuse, abuse, and over-prescription of opioids.

4 2. Since 2000, more than 400,000 Americans have lost their lives to an opioid  
5 overdose, more than five times as many American lives as were lost in the entire Vietnam War.  
6 On any given day, 134 people will die from opioid overdoses in the United States. Drug  
7 overdoses are now the leading cause of death for Americans under age fifty. The recent increases  
8 in drug overdose deaths have been so steep that they have contributed to reductions in the  
9 country's life expectancy over the last three years, a pattern unprecedented since World War II.

10 3. The opioid crisis has become a public health emergency. Plaintiff City of  
11 Spokane, with over 220,000 residents, has been deeply affected by the crisis. The opioid abuse  
12 prevalent throughout the City has affected Plaintiff in numerous ways, through increased drug-  
13 related offenses affecting law enforcement and the municipal court, as well as through additional  
14 resources spent on community and social programs, including for the next generation of Spokane  
15 residents, who are growing up in the shadow of the opioid epidemic.

16 4. While the City has committed considerable resources to deal with the crisis, fully  
17 addressing the crisis requires that those responsible for it pay for their conduct and to abate the  
18 nuisance and harms they have created in Spokane.

19 5. The opioid epidemic is no accident. On the contrary, it is the foreseeable  
20 consequence of Defendants' reckless and misleading promotion of potent narcotics as safe and  
21 effective treatment for pain and their relentless distribution of hundreds of millions of pills into  
22 American communities when they knew or should have known those pills were being diverted to  
23 illicit use.

24 6. Purdue Pharma, L.P., Purdue Pharma, Inc. and The Purdue Frederick Company,  
25 Inc. (hereafter "Purdue") set the stage for the opioid epidemic, through the production and  
26 promotion of its blockbuster drug, OxyContin. Purdue sought Chapter 11 bankruptcy protection  
27 on September 15, 2019, and thus is not named as a defendant here.

1           7.       Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A.  
2 Sackler, Ilene Sackler Lefcourt, the late Beverly Sackler, Theresa Sackler, David A. Sackler, and  
3 the Trust for the Benefit of Members of the Raymond Sackler Family (hereafter “Sacklers” or  
4 “Sackler Family”) are or were variously the direct or indirect operators, owners, or relatives of  
5 the owners, of Purdue and/or its affiliates. The Sacklers are currently protected from suit by a  
6 preliminary injunction entered by the Bankruptcy Court in the Purdue bankruptcy on October 11,  
7 2019, and thus are not named as defendants here.

8           8.       Purdue’s affiliate Rhodes Pharmaceuticals L.P. and Rhodes Pharmaceuticals Inc.  
9 marketed generic prescription opioids, including a generic version of OxyContin. Rhodes  
10 Technologies manufactured and supplied oxycodone, the active pharmaceutical ingredient in  
11 OxyContin, for use in the manufacture of pharmaceutical preparations. Rhodes Technologies,  
12 Inc. manufactured and supplied oxycodone to Purdue, or has managed Rhodes Technologies in  
13 doing so. Rhodes Pharmaceuticals L.P., Rhodes Pharmaceuticals Inc., Rhodes Technologies, and  
14 Rhodes Technologies, Inc. are referred to herein collectively as “Rhodes.”

15           9.       Rhodes Pharmaceuticals, L.P. and Rhodes Technologies sought Chapter 11  
16 bankruptcy protection along with Purdue on September 15, 2019, and thus are not named as  
17 defendants here. Rhodes Pharmaceuticals, Inc. and Rhodes Technologies, Inc. are currently  
18 protected from suit by a preliminary injunction entered by the Bankruptcy Court in the Purdue  
19 bankruptcy on October 11, 2019, and thus are not named as defendants here.

20           10.      Purdue introduced a drug with a narcotic payload many times higher than that of  
21 previous prescription painkillers, while executing a sophisticated, multi-pronged marketing  
22 campaign to change prescribers’ perception of the risk of opioid addiction and to portray opioids  
23 as effective treatment for chronic pain. Purdue pushed its message of opioids as a low-risk  
24 panacea on doctors and the public through every available avenue, including through direct  
25 marketing, front groups, key opinion leaders, unbranded advertising, and hundreds of sales  
26 representatives who visited doctors and clinics on a regular basis.

11. As sales of OxyContin and Purdue’s profits surged, Defendants Endo, Janssen, Teva, Actavis, and Mallinckrodt—as explained in further detail below— added additional prescription opioids, aggressive sales tactics, and dubious marketing claims of their own to the deepening crisis. They paid hundreds of millions of dollars to market and promote the drugs, notwithstanding their dangers, and pushed bought-and-paid-for “science” supporting the safety and efficacy of opioids that lacked any basis in fact or reality. Obscured from the marketing was the fact that prescription opioids are not much different than heroin—indeed on a molecular level, they are virtually indistinguishable.

12. The opioid epidemic simply could not have become the crisis it is today without an enormous supply of pills. After the aggressive and misleading marketing of branded opioids like OxyContin and Opana ignited the epidemic, generic opioids fanned the flames. Rhodes and Defendants Mallinckrodt, Actavis, Teva, and Endo manufactured and shipped enormous volumes of generic opioids to communities across the United States, including Plaintiff’s. Defendants McKesson, Cardinal Health, and AmerisourceBergen raked in huge profits from the distribution of branded and generic opioids alike. These companies knew precisely the quantities of potent narcotics they were delivering to communities across the country, including Spokane. Yet not only did these Defendants intentionally disregard their monitoring and reporting obligations under federal law, they also actively sought to evade restrictions and obtain higher quotas to enable the distribution of even larger shipments of opioids.

13. Defendants’ efforts were remarkably successful: since the mid-1990s, opioids have become the most prescribed class of drugs in America. Between 1991 and 2011, opioid prescriptions in the U.S. tripled from 76 million to 219 million per year.<sup>1</sup> In 2013, health care providers wrote more than 249 million prescriptions for opioid pain medication, enough for

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<sup>1</sup> Nora D. Volkow, MD, *America’s Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH Nat’l Inst. on Drug Abuse (May 14, 2014), <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.



every adult in the United States to have more than one bottle of pills.<sup>2</sup> In terms of annual sales, the increase has been ten-fold; before the FDA approved OxyContin in 1995, annual opioid sales hovered around \$1 billion. By 2015, they increased to almost \$10 billion. By 2020, revenues are projected to grow to \$18 billion.<sup>3</sup>

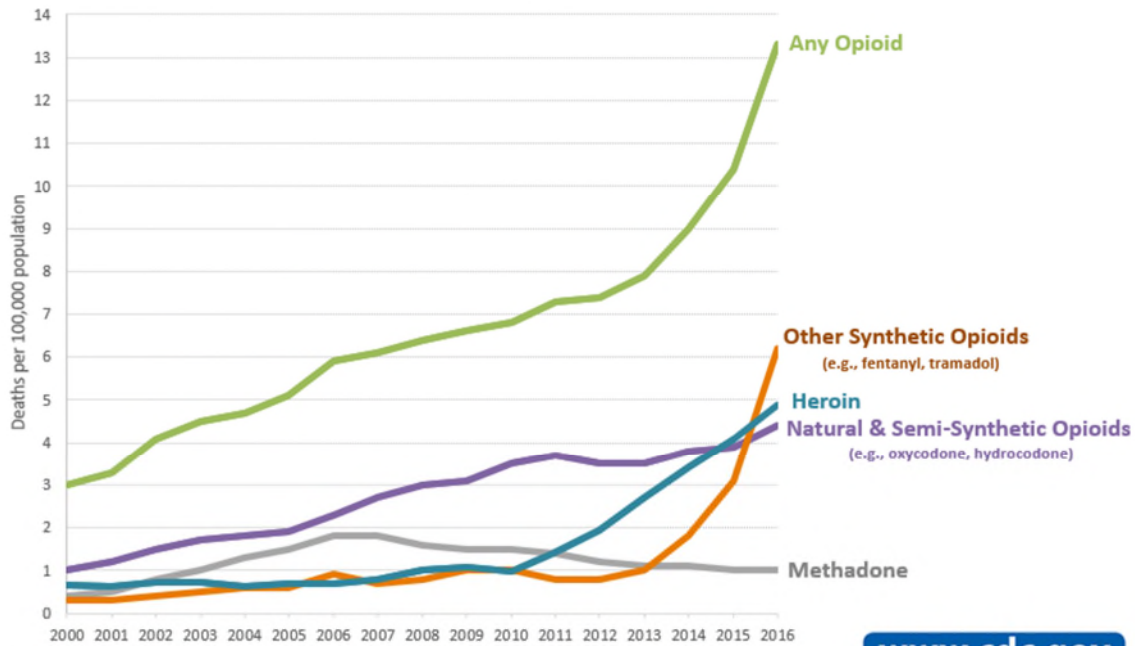
14. But Defendants' profits have come at a steep price. Opioids are now the leading cause of accidental death in the U.S., surpassing deaths caused by car accidents. Opioid overdose deaths (which include prescription opioids as well as heroin) have risen steeply over the past two decades, from approximately 8,048 in 1999, to 20,422 in 2009, to over 33,091 in 2015. The epidemic of overdose deaths shows no sign of slowing: instead, the grim toll climbed to 42,249 in 2016, and to 49,068 in 2017.<sup>4</sup> As shown in the graph below, the surge in opioid-related deaths in the past few years is tied to synthetic opioids such as fentanyl, which is many times more powerful than other opioids but often illicitly manufactured to look like generic oxycodone. Fatal overdoses involving heroin have also increased significantly since 2011. Nearly half of all opioid overdose deaths involve a prescription opioid like those manufactured by Defendants,<sup>5</sup> and, as discussed further below, the increase in overdoses from non-prescription opioids such as heroin and illicitly manufactured fentanyl is directly attributable to Defendants' success in expanding the market for opioids of any kind.

<sup>2</sup> CDC Guideline for Prescribing Opioids for Chronic Pain, Ctrs. for Disease Control and Prevention, [https://www.cdc.gov/drugoverdose/pdf/guidelines\\_at-a-glance-a.pdf](https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf) (last visited Aug. 30, 2019).

<sup>3</sup> Report: Opioid pain sales to hit \$18.4B in the U.S. by 2020, CenterWatch (July 17, 2017), <https://www.centerwatch.com/news-online/2017/07/17/report-opioid-pain-sales-hit-18-4b-u-s-2020/>.

<sup>4</sup> Overdose Death Rates, NIH Nat'l Inst. on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Jan. 2019); Drug Overdose Death Data, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last reviewed June 27, 2019).

<sup>5</sup> Understanding the Epidemic, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last reviewed Dec. 19, 2018).

**Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016**

SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2017.  
<https://wonder.cdc.gov/>.

**www.cdc.gov**  
 Your Source for Credible Health Information

15. To put these numbers in perspective: in 1970, when a heroin epidemic swept the U.S., there were fewer than 3,000 heroin overdose deaths. And in 1988, around the height of the crack epidemic, there were fewer than 5,000 crack overdose deaths recorded. In 2005, at its peak, methamphetamine was involved in approximately 4,500 deaths.

16. Beyond the human cost, the CDC has estimated that the total economic burden of prescription opioid abuse costs the United States \$78.5 billion per year, which includes increased costs for health care and addiction treatment, increased strains on human services and criminal justice systems, and substantial losses in workforce productivity.<sup>6</sup>

17. But even these estimates are conservative. The Council of Economic Advisers—the primary advisor to the Executive Office of the President—recently issued a report estimating that as of 2015, the economic cost of the opioid crisis was \$504 billion—over six times larger

<sup>6</sup> CDC Foundation's *New Business Pulse Focuses on Opioid Overdose Epidemic*, Ctrs. for Disease Control and Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-Business-Pulse-opioids.html>.

1 than the most comprehensive study that preceded it.<sup>7</sup> Whatever the final tally, there is no doubt  
2 that this crisis has had a profound economic impact.

3 18. Defendants orchestrated this crisis. Despite knowing about the true hazards of  
4 their products, Defendants misleadingly advertised their opioids as safe and effective for treating  
5 chronic pain and pushed hundreds of millions of pills into the marketplace for consumption.  
6 Through their sophisticated and well-orchestrated campaign, Defendants touted the purported  
7 benefits of opioids to treat pain and downplayed the risks of addiction. Moreover, even as the  
8 deadly toll of prescription opioid use became apparent to Defendants in years following  
9 OxyContin's launch, Defendants persisted in aggressively selling and distributing prescription  
10 opioids while evading their monitoring and reporting obligations, so that excessive quantities of  
11 addictive opioids continued to pour into Spokane and other communities around the United  
12 States.

13 19. Defendants consistently, deliberately, and recklessly made and continue to make  
14 false and misleading statements regarding, among other things, the low risk of addiction to  
15 opioids, opioids' effectiveness for chronic pain and ability to improve patients' quality of life  
16 with long-term use, the lack of risk associated with higher dosages of opioids, the need to  
17 prescribe more opioids to treat withdrawal symptoms, and that risk-mitigation strategies and  
18 abuse-deterrent technologies allow doctors to safely prescribe opioids. In addition, Defendants  
19 made and continued to make misleading representations about their compliance with their  
20 obligations to maintain effective controls against diversion and to report suspicious orders in  
21 connection with the sale of opioids.

22 20. Because of Defendants' misconduct, Spokane is experiencing substantial public  
23 health and other impacts and has suffered significant economic damages, including but not  
24

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25 <sup>7</sup> *The Underestimated Cost of the Opioid Crisis*, The Council of Econ. Advisers (Nov. 2017),  
26 <https://static.politico.com/1d/33/4822776641cfbac67f9bc7dbd9c8/the-underestimated-cost-of-the-opioid-crisis-embargoed.pdf>; Curtis Florence, Feijun Luo, Chao Zhou, & Likang Xu, *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013*, 54 Med. Care 901 (Oct. 2016),  
27 [https://www.researchgate.net/publication/308339245\\_The\\_Economic\\_Burden\\_of\\_Prescription\\_Opioid\\_Overdose\\_Abuse\\_and\\_Dependence\\_in\\_the\\_United\\_States\\_2013](https://www.researchgate.net/publication/308339245_The_Economic_Burden_of_Prescription_Opioid_Overdose_Abuse_and_Dependence_in_the_United_States_2013).

1 limited to increased costs related to opioid-related crimes and emergencies, criminal justice, and  
 2 public safety. Spokane has incurred substantial costs in responding to the crisis and will continue  
 3 to do so in the future.

4 21. Accordingly, Spokane brings this action to hold Defendants liable for their  
 5 misrepresentations regarding the benefits and risks of prescription opioids, as well as for their  
 6 failure to monitor, detect, investigate, and report suspicious orders of those products. This  
 7 conduct (i) violates the Washington Consumer Protection Act, RCW 19.86 *et seq.*, (ii)  
 8 constitutes a public nuisance under Washington law, (iii) constitutes negligence under  
 9 Washington law, (iv) has unjustly enriched Defendants, and (v) violates the Racketeer Influenced  
 10 and Corrupt Organizations Act (“RICO”), 18 U.S.C. § 1961 *et seq.*

## 11 II. PARTIES

### 12 Spokane

13 22. Plaintiff City of Spokane is located in Spokane County, Washington. Spokane is  
 14 incorporated as a Charter City organized under the Strong Mayor form of government pursuant  
 15 to RCW 35.22.200.

### 16 Endo

17 23. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant  
 18 Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business  
 19 in Malvern, Pennsylvania. Collectively, these entities are referred to as “Endo.”

20 24. Each Endo entity acted in concert with one another and acted as agents and/or  
 21 principals of one another in connection with the conduct described herein.

22 25. Endo manufactures, promotes, sells, markets, and distributes opioids such as  
 23 Percocet, Opana, and Opana ER.

24 26. Endo generates substantial sales from its opioids. For example, opioids accounted  
 25 for more than \$400 million of Endo’s overall revenues of \$3 billion in 2012, and Opana ER  
 26 generated more than \$1 billion in revenue for Endo in 2010 and 2013.

**Janssen and Johnson & Johnson**

27. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Collectively, these entities are referred to as “Janssen.”

28. Both entities above acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

29. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

30. Janssen manufactures, promotes, sells, markets, and distributes opioids such as Duragesic, Nucynta, and Nucynta ER. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

31. Janssen generates substantial sales revenue from its opioids. For example, Duragesic accounted for more than \$1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

**Cephalon and Teva**

32. Defendant Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation and a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

33. Cephalon manufactures, promotes, sells, and distributes opioids, including Actiq and Fentora, in the United States.

34. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which are distributed with Cephalon opioids, disclose that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

35. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.<sup>8</sup> Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012—the year following the Cephalon acquisition in October 2011—attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including sales of Fentora.<sup>9</sup> Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies’ business in the United States itself.

36. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Collectively, these entities are referred to as “Teva.”

### **Allergan, Actavis, and Watson**

37. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company changed its name to Allergan plc in June 2015. Actavis plc

<sup>8</sup> Actiq, <http://www.actiq.com/> (last visited Aug. 30, 2019).

<sup>9</sup> *Teva Pharm. Indus. Ltd. Form 20-F*, U.S. Sec. and Exchange Commission (Feb. 12, 2013), [http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ\\_TEVA\\_2012.pdf](http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf).

1 (formerly known as Actavis Limited) was incorporated in Ireland in May 2013 for the merger  
2 between Actavis, Inc. and Warner Chilcott plc.

3 38. Defendant Watson Pharmaceuticals, Inc. acquired Actavis Group in October 2012  
4 and changed its name to Actavis, Inc. as of January 2013.

5 39. Defendant Allergan Finance, LLC (formerly known as Actavis, Inc.) is based in  
6 Parsippany, New Jersey. It operates as a subsidiary of Allergan plc.

7 40. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal  
8 place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a  
9 Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

10 41. Defendant Actavis Pharma, Inc. is registered to do business in the State of  
11 Washington as a Delaware corporation with its principal place of business in New Jersey and  
12 was formerly known as Watson Pharma, Inc.

13 42. Defendant Actavis LLC is a Delaware limited liability company with its principal  
14 place of business in Parsippany, New Jersey.

15 43. Each of these defendants and entities is owned by Defendant Allergan plc, which  
16 uses them to market and sell its drugs in the United States. Upon information and belief,  
17 Defendant Allergan plc exercises control over these marketing and sales efforts and profits from  
18 the sale of Allergan/Actavis/Watson products ultimately inure to its benefit. Collectively, these  
19 defendants and entities are referred to as "Actavis."

20 44. Actavis manufactures, promotes, sells, and distributes opioids in the United  
21 States, including the branded drugs Kadian and Norco and generic versions of Kadian,  
22 Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on  
23 December 30, 2008, and began marketing Kadian in 2009.

24 **Mallinckrodt**

25 45. Defendant Mallinckrodt plc is an Irish public limited company headquartered in  
26 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.  
27 Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the



1 pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt in June of  
 2 that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt &  
 3 Co. in 1867; Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare  
 4 Group separated from Tyco International and renamed itself Covidien.

5 46. Defendant Mallinckrodt, LLC is a limited liability company organized and  
 6 existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned  
 7 subsidiary of Mallinckrodt plc.

8 47. Formed in 2017, Defendant SpecGX LLC is a Delaware limited liability company  
 9 with its principal place of business in St. Louis, Missouri, and is a wholly owned subsidiary of  
 10 Defendant Mallinckrodt plc. SpecGX LLC manufactures Mallinckrodt's generic products and  
 11 bulk active pharmaceutical ingredients (APIs).

12 48. Mallinckrodt plc, Mallinckrodt, LLC, and SpecGX LLC are referred to  
 13 collectively as "Mallinckrodt."

14 49. Mallinckrodt manufactures, markets, and sells drugs in the United States. As of  
 15 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the  
 16 largest manufacturers of oxycodone in the U.S.

17 50. Mallinckrodt currently manufactures and markets two branded opioids: Exalgo,  
 18 which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and  
 19 Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In addition,  
 20 Mallinckrodt previously developed, promoted, and sold the following branded opioid products:  
 21 Magnacet, TussiCaps, and Xartemis XR.

22 51. While it has sought to develop its branded opioid products, Mallinckrodt has long  
 23 been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received  
 24 approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota  
 25 for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health  
 26 data for the same period, that its generics claimed an approximately 23% market share of DEA  
 27 Schedules II and III opioid and oral solid dose medications.



52. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials; (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York; and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

53. In 2017, Mallinckrodt agreed to settle for \$35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged that even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA").

**Par Pharmaceutical**

54. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Defendant Par Pharmaceutical Companies, Inc. and holds itself out as "an Endo International Company."

55. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York.

56. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively as "Par Pharmaceutical." Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc.

57. At all relevant times, Par Pharmaceutical has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, Par Pharmaceutical manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

1           58.     Based on the private ARCOS data made available to Plaintiff, drugs sold and  
2 manufactured by Par Pharmaceutical represent a substantial market share in Plaintiff's  
3 jurisdiction during the relevant time period.

4           59.     Par Pharmaceutical's conduct thus directly caused the worst man-made epidemic  
5 in modern medical history—the misuse, abuse, and over-prescription of opioids across this  
6 country, including in this jurisdiction.

7           **Mylan Pharmaceuticals, Inc.**

8           60.     Defendant Mylan Pharmaceuticals, Inc. ("Mylan"), is a West Virginia corporation  
9 with its principal place of business in Canonsburg, Pennsylvania.

10          61.     At all relevant times, Mylan has packaged, distributed, supplied, sold, placed into  
11 the stream of commerce, labeled, described, marketed, advertised, promoted and purported to  
12 warn or purported to inform prescribers and users regarding the benefits and risks associated  
13 with the use of the prescription opioid drugs. Further, Mylan manufactured and sold prescription  
14 opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

15          62.     Based on the private ARCOS data made available to Plaintiff, drugs sold and  
16 manufactured by Mylan represent a substantial market share in Plaintiff's jurisdiction during the  
17 relevant time period.

18          63.     Mylan's conduct thus directly caused the worst man-made epidemic in modern  
19 medical history—the misuse, abuse, and over-prescription of opioids across this country,  
20 including in this jurisdiction.

21           **West-Ward Pharmaceuticals Corp.**

22          64.     Defendant West-Ward Pharmaceuticals Corp. is a Delaware corporation with its  
23 principal place of business located in Eatontown, New Jersey. West-Ward Pharmaceuticals Corp.  
24 is the United States agent and subsidiary of Defendant Hikma Pharmaceuticals PLC, a London-  
25 based global pharmaceutical company.

26          65.     West-Ward Pharmaceuticals Corp. and Hikma Pharmaceuticals PLC are  
27 collectively referred to as "West-Ward."

1           66. At all relevant times, West-Ward has packaged, distributed, supplied, sold, placed  
2 into the stream of commerce, labeled, described, marketed, advertised, promoted and purported  
3 to warn or purported to inform prescribers and users regarding the benefits and risks associated  
4 with the use of the prescription opioid drugs. Further, West-Ward manufactured and sold  
5 prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious  
6 orders.

7           67. Based on the private ARCOS data made available to Plaintiff, drugs sold and  
8 manufactured by West-Ward represent a substantial market share in Plaintiff's jurisdiction  
9 during the relevant time period.

10          68. West-Ward's conduct thus directly caused the worst man-made epidemic in  
11 modern medical history—the misuse, abuse, and over-prescription of opioids across this country,  
12 including in this jurisdiction.

13          69. Defendants Endo, Janssen, Teva, Actavis, and Mallinckrodt are collectively  
14 referred to as the "Marketing Defendants." These Marketing Defendants together with Par  
15 Pharmaceutical, Mylan, and West-Ward are collectively referred to as the "Manufacturing  
16 Defendants."

17           **AmerisourceBergen**

18          70. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a  
19 Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania.

20          71. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest  
21 global pharmaceutical sourcing and distribution services companies" with "over \$145 billion in  
22 annual revenue."

23          72. AmerisourceBergen is licensed as a "wholesale distributor" to sell prescription  
24 and non-prescription drugs, including opioids, in Washington.

25           **Cardinal Health**

26          73. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio Corporation with  
27 its principal place of business in Dublin, Ohio.

1           74. According to its 2017 Annual Report, Cardinal Health is “a global, integrated  
2 healthcare services and products company serving hospitals, healthcare systems, pharmacies,  
3 ambulatory surgery centers, clinical laboratories and physician offices worldwide . . .  
4 deliver[ing] medical products and pharmaceuticals.” In 2017 alone, Cardinal Health generated  
5 revenues of nearly \$130 billion.

6           75. Cardinal Health is licensed as a “wholesale distributor” to sell prescription and  
7 non-prescription drugs, including opioids, in Washington.

8           **McKesson**

9           76. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with  
10 its principal place of business in San Francisco, California.

11           77. McKesson is the largest pharmaceutical distributor in North America, delivering  
12 nearly one-third of all pharmaceuticals used in this region.

13           78. According to its 2017 Annual Report, McKesson “partner[s] with pharmaceutical  
14 manufacturers, providers, pharmacies, governments and other organizations in healthcare to help  
15 provide the right medicines, medical products and healthcare services to the right patients at the  
16 right time, safely and cost-effectively.” Additionally, McKesson’s pharmaceutical distribution  
17 business operates and serves thousands of customer locations through a network of twenty-seven  
18 distribution centers, as well as a primary redistribution center, two strategic redistribution centers  
19 and two repackaging facilities, serving all fifty states and Puerto Rico.

20           79. For the fiscal year ending March 31, 2017, McKesson generated revenues of  
21 \$198.5 billion.

22           80. McKesson is licensed as a “wholesale distributor” to sell prescription and non-  
23 prescription drugs, including opioids, in Washington.

24           81. Collectively, McKesson, AmerisourceBergen, and Cardinal Health account for  
25 approximately 85% of all drug shipments in the United States.

1           **Walgreens**

2           82. Defendant Walgreens Boots Alliance Inc. a/k/a Walgreen Co. (“Walgreens”) is a  
3 Delaware corporation with its principal place of business in Illinois. Walgreens, through its  
4 various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed  
5 wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription  
6 opioids throughout the United States, including in Plaintiff’s communities.

7           83. Based on the private ARCOS data made available to Plaintiff, drugs sold and  
8 distributed by Walgreens represent a substantial market share in Plaintiff’s jurisdiction during the  
9 relevant time period.

10          84. Walgreens’ conduct thus directly caused the worst man-made epidemic in modern  
11 medical history—the misuse, abuse, and over-prescription of opioids across this country,  
12 including in this jurisdiction.

13           **Thrifty Payless**

14          85. Defendant Thrifty Payless, Inc. is a California corporation with its principal place  
15 of business in Camp Hill, Pennsylvania and is a subsidiary of Rite Aid Corporation.

16          86. At all times relevant to this Complaint, Thrifty Payless, Inc. was in the business of  
17 distributing and redistributing prescription opioids throughout the United States, including in this  
18 jurisdiction.

19          87. Thrifty Payless, Inc. and Rite Aid Corporation are referred to collectively as  
20 “Thrifty Payless.”

21          88. Based on the private ARCOS data made available to Plaintiff, drugs sold and  
22 distributed by Thrifty Payless represent a substantial market share in Plaintiff’s jurisdiction  
23 during the relevant time period.

24          89. Thrifty Payless’s conduct thus directly caused the worst man-made epidemic in  
25 modern medical history—the misuse, abuse, and over-prescription of opioids across this country,  
26 including in this jurisdiction.

**Omnicare**

90. Defendant Omnicare Distribution Center LLC is a Delaware limited liability company with its headquarters and principal place of business in Cincinnati, Ohio.

91. At all times relevant to this Complaint, Omnicare Distribution Center LLC was in the business of distributing and redistributing prescription opioids throughout the United States, including in this jurisdiction.

92. Based on the private ARCOS data made available to Plaintiff(s), drugs sold and distributed by Omnicare Distribution Center LLC represent a substantial market share in Plaintiff's jurisdiction during the relevant time period.

93. Omnicare Distribution Center LLC's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

**CVS**

94. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island.

95. Defendant CVS Pharmacy Inc. is a Rhode Island corporation with its principal place of business in Rhode Island.

96. CVS Health Corporation conducts business as a licensed wholesale distributor under the name of Defendant CVS RX Services, Inc., among others.

97. CVS Health Corporation, CVS Pharmacy Inc., CVS RX Services, Inc., and all related entities including all predecessors and successors and subsidiaries, including but not limited to Defendant Omnicare, Inc., are referred to collectively as "CVS".

98. CVS, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Plaintiff's communities.

1           99. Based on the private ARCOS data made available to Plaintiff(s), drugs sold and  
2 distributed by CVS represent a substantial market share in Plaintiff's jurisdiction during the  
3 relevant time period.

4           100. CVS's conduct thus directly caused the worst man-made epidemic in modern  
5 medical history—the misuse, abuse, and over-prescription of opioids across this country,  
6 including in this jurisdiction.

7           101. McKesson, AmerisourceBergen, Cardinal Health, Walgreens, Thrifty Payless,  
8 Omnicare, and CVS collectively are referred to as the "Distributor Defendants."

9           **John and Jane Does 1-100, inclusive**

10          102. In addition to the Defendants identified herein, the true names, roles, and/or  
11 capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through  
12 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under  
13 fictitious names as permitted by the rules of this Court. Plaintiff will amend this complaint and  
14 identify their true identities and their involvement in the wrongdoing at issue, as well as the  
15 specific causes of action asserted against them when they become known.

16                                   **III. JURISDICTION AND VENUE**

17          103. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The  
18 Court also has federal question subject matter jurisdiction arising out of Plaintiff's RICO claims  
19 pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq.*

20          104. Venue in this Court is proper under 28 U.S.C. § 1391(b).

21                                   **IV. FACTUAL ALLEGATIONS**

22          **A. History and Background of Medical Use of Opioids**

23          105. The term "opioid" refers to a class of drugs that bind with opioid receptors in the  
24 brain and includes natural, synthetic, and semi-synthetic opioids.<sup>10</sup> Generally used to treat pain,

25 \_\_\_\_\_  
26 <sup>10</sup> At one time, the term "opiate" was used for natural opioids, while "opioid" referred to synthetic substances  
27 manufactured to mimic opiates. Now, however, most medical professionals use "opioid" to refer broadly to  
natural, semi-synthetic, and synthetic opioids. A fourth class of opioids, endogenous opioids (e.g., endorphins), is  
produced naturally by the human body.

1 opioids produce multiple effects on the human body, the most significant of which are analgesia,  
2 euphoria, and respiratory depression. In addition, opioids cause sedation and constipation.

3 106. Most of these effects are medically useful in certain situations, but respiratory  
4 depression is the primary limiting factor for the use of opioids. While the body develops  
5 tolerance to the analgesic and euphoric effects of opioids relatively quickly, this is not true with  
6 respect to respiratory depression. At high doses, opioids can and often do arrest respiration  
7 altogether. This is why the risk of opioid overdose is so high, and why many of those who  
8 overdose simply go to sleep and never wake up.

9 107. Natural opioids are derived from the opium poppy and have been used since  
10 antiquity, going as far back as 3400 B.C. The opium poppy contains various opium alkaloids,  
11 three of which are used commercially today: morphine, codeine, and thebaine.

12 108. A 16th-century European alchemist, Paracelsus, is generally credited with  
13 developing a tincture of opium and alcohol called laudanum, but it was a British physician a  
14 century later who popularized the use of laudanum in Western medicine. "Sydenham's  
15 laudanum" was a simpler tincture than Paracelsus's and was widely adopted as a treatment not  
16 only for pain, but for coughs, dysentery, and numerous other ailments. Laudanum contains  
17 almost all of the opioid alkaloids and is still available by prescription today.

18 109. Chemists first isolated the morphine and codeine alkaloids in the early 1800s, and  
19 the pharmaceutical company Merck began large-scale production and commercial marketing of  
20 morphine in 1827. During the American Civil War, field medics commonly used morphine,  
21 laudanum, and opium pills to treat the wounded, and many veterans were left with morphine  
22 addictions. It was upper- and middle-class white women, however, who comprised the majority  
23 of opioid addicts in the late 19th-century United States, using opioid preparations widely  
24 available in pain elixirs, cough suppressants, and patent medicines. By 1900, an estimated  
25  
26  
27



1 300,000 people were addicted to opioids in the United States,<sup>11</sup> and many doctors prescribed  
2 opioids solely to prevent their patients from suffering withdrawal symptoms.

3 110. Trying to develop a drug that could deliver opioids' potent pain relief without  
4 their addictive properties, chemists continued to isolate and refine opioid alkaloids. Heroin, first  
5 synthesized from morphine in 1874, was marketed commercially by the Bayer Pharmaceutical  
6 Company beginning in 1898 as a safe alternative to morphine. Heroin's market position as a safe  
7 alternative was short-lived, however; Bayer stopped mass-producing heroin in 1913 because of  
8 its dangers. German chemists then looked to the alkaloid thebaine, synthesizing oxymorphone  
9 and oxycodone from thebaine in 1914 and 1916, respectively, with the hope that the different  
10 alkaloid source might provide the benefits of morphine and heroin without the drawbacks.

11 111. But each opioid was just as addictive as the one before it, and eventually the issue  
12 of opioid addiction could not be ignored. The nation's first Opium Commissioner, Hamilton  
13 Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our  
14 prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of  
15 moral sense and made them beasts who prey upon their fellows . . . it has become one of the  
16 most fertile causes of unhappiness and sin in the United States."<sup>12</sup>

17 112. Concerns over opioid addiction led to national legislation and international  
18 agreements regulating narcotics: the International Opium Convention, signed at the Hague in  
19 1912, and, in the U.S., the Harrison Narcotics Tax Act of 1914. Opioids were no longer marketed  
20 as cure-alls and instead were relegated to the treatment of acute pain.

21 113. Throughout the twentieth century, pharmaceutical companies continued to  
22 develop prescription opioids, but these opioids were generally produced in combination with  
23 other drugs, with relatively low opioid content. For example, Percodan, produced by Defendant  
24 Endo since 1950, is oxycodone and aspirin, and contains just under 5 mg of oxycodone.

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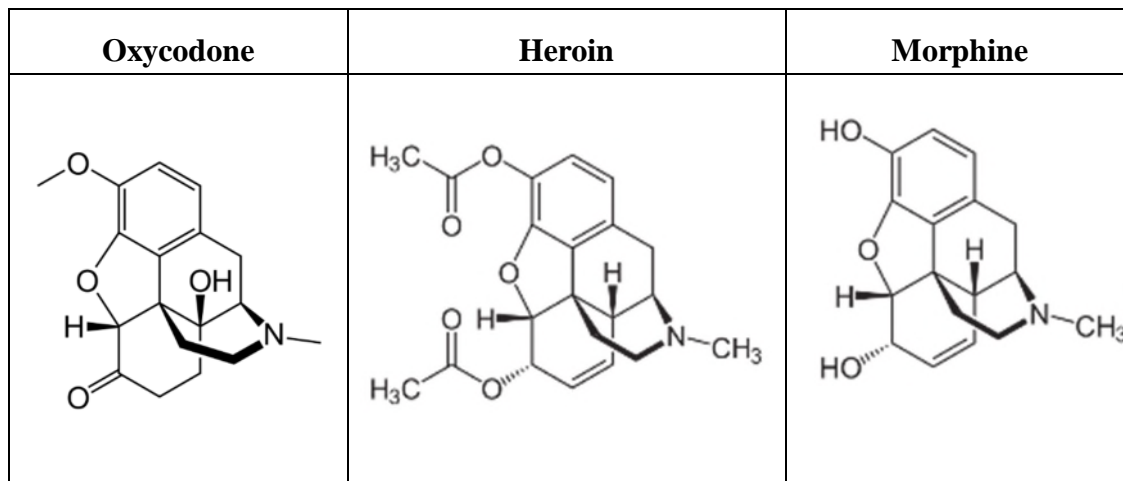
25  
26 <sup>11</sup> Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*,  
Washington Post (Oct. 17, 2017), [https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-](https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca)  
27 [drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm\\_term=.7832633fd7ca](https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca).

<sup>12</sup> *Id.*

Percocet, manufactured by Endo since 1971, is the combination of oxycodone and acetaminophen, with dosage strengths delivering between 2.5 mg and 10 mg of oxycodone. Vicodin, a combination of hydrocodone and acetaminophen, was introduced in the U.S. in 1978 and is sold in strengths of 5 mg, 7.5 mg, and 10 mg of hydrocodone. Defendant Janssen also manufactured a drug with 5 mg of oxycodone and 500 mg of acetaminophen, called Tylox, from 1984 to 2012.

114. In contrast, OxyContin, the product with the dubious honor of the starring role in the opioid epidemic, is pure oxycodone. Purdue initially made it available in the following dosage strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. In other words, the weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times as much as that.

115. Prescription opioids are essentially pharmaceutical heroin; they are synthesized from the same plant, have similar molecular structures, and bind to the same receptors in the human brain. It is no wonder then that there is a straight line between prescription opioid abuse and heroin addiction. Indeed, studies show that over 80% of new heroin addicts between 2008 and 2010 started with prescription opioids.<sup>13</sup>



<sup>13</sup> CM Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010*, 132(1-2) Drug Alcohol Depend. 95-100 (Sept. 1, 2013), <https://www.ncbi.nlm.nih.gov/pubmed/23410617>.

116. Medical professionals describe the strength of various opioids in terms of “morphine milligram equivalents” (“MME”). According to the CDC, dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

117. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin’s twice-daily dosing, the 50 MME/day threshold is reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.<sup>14</sup>

118. As journalist Barry Meier wrote in his 2003 book *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death*, “In terms of narcotic firepower, OxyContin was a nuclear weapon.”<sup>15</sup>

119. Fentanyl, an even more potent and more recent arrival in the opioid tale, is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959 by Dr. Paul Janssen under a patent held by Janssen Pharmaceuticals, fentanyl is increasingly prevalent in the market for opioids created by Defendants’ promotion, with particularly lethal consequences. In many instances, illicit fentanyl is manufactured to look like oxycodone tablets, in the light blue color and with the “M” stamp of Defendant Mallinckrodt’s 30mg oxycodone pills. These lookalike pills have been found around the country.<sup>16</sup>

<sup>14</sup> The wide variation in the MME strength of prescription opioids renders misleading any effort to capture “market share” by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focused its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

<sup>15</sup> Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* (Rodale 2003).

<sup>16</sup> See e.g., Sharon Bogan, *Illicit fentanyl found locally in fake opioid pills*, Public Health Insider (Oct. 2, 2017), <https://web.archive.org/web/20190804203642/https://publichealthinsider.com/2017/10/02/illicit-fentanyl-found-locally-in-fake-opioid-pills/>; *Mislabeled painkillers “a fatal overdose waiting to happen,”* CBS News (Feb. 29, 2016, 10:46am), <https://www.cbsnews.com/news/mislabeled-painkillers-a-fatal-overdose-waiting-to-happen/>.

**B. The Sackler Family Played a Pivotal Role in Setting the Stage for the Worst Man-Made Epidemic in Modern Medical History**

**1. The Sackler family pioneered the integration of advertising and medicine.**

120. Given the history of opioid use in the U.S. and the medical profession's resulting wariness, the commercial success of Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

121. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, surpassing the wealth of storied families like the Rockefellers, the Mellons, and the Busches.<sup>17</sup> Because of Purdue and, in particular, OxyContin, the Sacklers' net worth was \$13 billion as of 2016. Until 2018, Sackler family members made up the majority of the Purdue board, and all of the company's profits go to Sackler family trusts and entities.<sup>18</sup> Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

122. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called The Purdue Frederick Company in 1952. While all three brothers were accomplished psychiatrists, it was Arthur, the oldest, who directed the Sackler story, treating his brothers more as his protégés than colleagues, putting them both through medical school and essentially dictating their paths. It was Arthur who created the Sackler family's wealth, and it was Arthur who created the pharmaceutical advertising industry as we know it—laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

<sup>17</sup> Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, *Forbes* (July 1, 2015, 10:17am), <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#3045688775e0>.

<sup>18</sup> David Armstrong, *The man at the center of the secret OxyContin files*, *Stat News* (May 12, 2016), <https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/>.

123. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. Arthur pioneered both print advertising in medical journals and promotion through physician “education” in the form of seminars and continuing medical education courses. He understood intuitively the persuasive power of recommendations from fellow physicians and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.<sup>19</sup>

124. It was Arthur who, in the 1960s, made Valium into the first \$100-million drug, so popular it became known as “Mother’s Little Helper.” His expertise as a psychiatrist was key to his success; as his biography in the Medical Advertising Hall of Fame notes, it “enabled him to position different indications for Roche’s Librium and Valium—to distinguish for the physician the complexities of anxiety and psychic tension.”<sup>20</sup> When Arthur’s client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called “psychic tension”—essentially stress—and pitched Valium as the solution.<sup>21</sup> The campaign, for which Arthur was compensated based on volume of pills sold,<sup>22</sup> was a remarkable success.

125. Arthur’s entrepreneurial drive led him to create not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which he distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing

<sup>19</sup> Meier, *supra* note 15, at 204.

<sup>20</sup> MAHF Inductees, Arthur M. Sackler, Med. Advert. Hall of Fame, <https://www.mahf.com/mahf-inductees/> (last visited Aug. 30, 2019).

<sup>21</sup> Meier, *supra* note 15, at 202; *One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), <http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids>.

<sup>22</sup> WBUR On Point interview, *supra* note 21.

practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Defendants, who utilize it to tailor their sales pitches to individual physicians.

126. Even as he expanded his business dealings, Arthur was adept at hiding his involvement in them. When, during a 1962 Senate hearing about deceptive pharmaceutical advertising, he was asked about a public relations company called Medical and Science Communications Associates, which distributed marketing from drug companies disguised as news articles, Arthur was able to truthfully testify that he never was an officer for nor had any stock in that company. But the company's sole shareholder was his then-wife. Around the same time, Arthur also successfully evaded an investigative journalist's attempt to link the Sacklers to a company called MD Publications, which had funneled payments from drug companies to an FDA official named Henry Welch, who was forced to resign when the scandal broke.<sup>23</sup> Arthur had set up such an opaque and layered business structure that his connection to MD Publications was only revealed decades later when his heirs were fighting over his estate.

127. Arthur Sackler did not hesitate to manipulate information to his advantage. His legacy is a corporate culture that prioritizes profits over people. In fact, in 2007, federal prosecutors conducting a criminal investigation of Purdue's fraudulent advertising of OxyContin found a "corporate culture that allowed this product to be misbranded with the intent to defraud and mislead."<sup>24</sup> Court documents from the prosecution state that "certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications . . ."<sup>25</sup> Half a century after Arthur Sackler wedded advertising and medicine, Purdue employees were following his playbook, putting product sales over patient safety.

<sup>23</sup> Meier, *supra* note 15, at 210-14.

<sup>24</sup> Naomi Spencer, *OxyContin manufacturer reaches \$600 million plea deal over false marketing practices*, World Socialist Web Site (May 19, 2007), <https://www.wsws.org/en/articles/2007/05/oxy-m19.html>.

<sup>25</sup> Agreed Statement of Facts, *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

1           **2. The Sacklers were personally involved in the development and aggressive**  
 2           **marketing of OxyContin.**

3           128. After the Sackler brothers acquired The Purdue Frederick Company in 1952,  
 4 Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable  
 5 business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in  
 6 running Purdue because that would have been a conflict of interest. Raymond Sackler became  
 7 Purdue's head executive while Mortimer Sackler ran Purdue's UK affiliate.

8           129. Raymond's son, Richard S. Sackler, began working for Purdue as an assistant to  
 9 the president in 1971. In addition to holding various other roles at Purdue, including leading the  
 10 firm's R&D division and the sales and marketing division, Richard Sackler was named president  
 11 in 1999. In 2003, Richard Sackler resigned from his role as president to become co-chair of  
 12 Purdue's board of directors.<sup>26</sup> He participated extensively in the invention, marketing, and sale of  
 13 OxyContin.

14           130. In addition to Richard Sackler's involvement, other members of the Sackler family  
 15 maintained substantial control over Purdue by occupying the majority of the board seats at Purdue  
 16 from 1990 to 2018. In 1999, when Richard Sackler became Purdue's president, Jonathan, Kathe,  
 17 and Mortimer Sackler were all vice presidents of Purdue.<sup>27</sup> Years later, when Purdue was mired in  
 18 investigations by federal and state authorities, they resigned their positions as vice presidents, but  
 19 they remained members of Purdue's board of directors. Ilene Sackler Lefcourt and Theresa Sackler  
 20 served on Purdue's board of directors beginning in the early 1990s. David A. Sackler served on  
 21 Purdue's board of directors beginning in 2012. Beverly Sackler, wife of Raymond Sackler, served  
 22 on Purdue's board from 1993 to 2017, resigning shortly after Raymond's death in 2017. Other  
 23  
 24  
 25

26 <sup>26</sup> Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017),  
<http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

27 <sup>27</sup> First Amended Complaint at ¶179, *Commonwealth of Mass. v. Purdue Pharma L.P.*, C.A. No. 1884-cv-01808  
 (BLS2) (Mass. Super. Ct. Jan. 31, 2019) ("MA Complaint").



1 Sackler family members resigned in 2018, and as of April 2019, according to Purdue, no Sackler  
2 family members remained on Purdue's board.<sup>28</sup>

3 131. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer  
4 that had developed a sustained-release technology suitable for morphine. Purdue marketed this  
5 extended-release morphine as MS Contin. It quickly became Purdue's best seller. As the patent  
6 expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time,  
7 Raymond Sackler's oldest son, Richard Sackler, who was also a trained physician, became more  
8 involved in the management of the company. Richard Sackler had grand ambitions for the  
9 company; according to a long-time Purdue sales representative, "Richard really wanted Purdue  
10 to be big—I mean *really* big."<sup>29</sup> Richard Sackler believed Purdue should develop another use for  
11 its "Contin" timed-release system.

12 132. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard  
13 Sackler and other executives recommending that the company work on a pill containing  
14 oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because  
15 it was most commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen  
16 combination pill. MS Contin was not only approaching patent expiration but had always been  
17 limited by the stigma associated with morphine. Oxycodone did not have that problem, and  
18 what's more, it was sometimes mistakenly called "oxycodine," which also contributed to the  
19 perception of relatively lower potency, because codeine is weaker than morphine. Purdue  
20 acknowledged using this to its advantage when it eventually pled guilty to criminal charges of  
21 "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many  
22 physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to  
23 make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . .  
24 . that would affect the unique position that OxyContin'" held among physicians.<sup>30</sup>

25 <sup>28</sup> Paul Schott, *Sacklers quit Purdue Pharma board amid shifts for OxyContin maker*, Stamford Advocate (Apr. 7,  
26 2019), <https://www.stamfordadvocate.com/business/article/Sacklers-quit-Purdue-Pharma-board-signaling-13742946.php>.

27 <sup>29</sup> Christopher Glazek, *supra* note 26.

<sup>30</sup> *United States v. Purdue Frederick Co.*, *supra* note 25.



1 133. Moreover, Purdue's internal emails reveal that Richard Sackler, Kathe Sackler, and  
 2 other Purdue executives personally knew that doctors incorrectly believed that OxyContin was  
 3 weaker than morphine, leading them to prescribe it much more frequently.<sup>31</sup> Despite knowing that  
 4 oxycodone is 1.5 times more potent than morphine, Richard Sackler directed staff not to tell  
 5 doctors the truth about oxycodone's potency—as that would have likely reduced sales.<sup>32</sup>

6 134. For Purdue and OxyContin to be “really big,” Purdue needed to both distance its  
 7 new product from the traditional view of narcotic addiction risk and broaden the drug's uses  
 8 beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in  
 9 March 1995 recommended that if Purdue could show that the risk of abuse was lower with  
 10 OxyContin than with traditional immediate-release narcotics, sales would increase.<sup>33</sup> As  
 11 discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue  
 12 from making that claim regardless.

13 135. The Sacklers recognized OxyContin as the means by which Purdue, and their own  
 14 fortune, could become “really big.” As Purdue's Senior Vice President in charge of sales, Richard  
 15 Sackler made an ominous prediction at the launch party for OxyContin. He foretold that “the  
 16 launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the  
 17 competition. The prescription blizzard will be so deep, dense, and white....”<sup>34</sup> To create this  
 18 “blizzard of prescriptions,” the Sacklers perpetuated deceptions about the safety of OxyContin and  
 19 pressed Purdue's sales team to sell ever-increasing volumes of OxyContin, incentivizing sales of  
 20 the more expensive (and more dangerous) higher doses.

21 136. Internal documents also reveal the extent to which the Sacklers' greed motivated  
 22 their unrelenting drive to sell more pills. For example, in one such email, Richard Sackler reacted  
 23 to sales of over \$20 million *per week* with a “yawn”:

25 <sup>31</sup> MA Complaint ¶ 176.

26 <sup>32</sup> *Id.*

<sup>33</sup> Meier, *supra* note 15, at 269.

27 <sup>34</sup> First Amended Complaint at ¶ 273, *The People of the State of New York v. Purdue Pharma L.P., et al.*, No. 400016/2018 (Sup. Ct. Suffolk Cnty. Mar. 28, 2019) (“NY Complaint”).

1 In 1999, when employee Michael Friedman reported to Richard Sackler that Purdue  
 2 was making more than \$20,000,000 per week, Richard replied immediately, at  
 3 midnight, that the sales were “not so great.” “After all, if we are to do 900M this  
 4 year, we should be running at 75M/month. So it looks like this month could be 80  
 5 or 90M. Blah, humbug. Yawn. Where was I?”<sup>35</sup>

6 137. Despite the fact that there has been little or no change in the amount of pain  
 7 reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market  
 8 for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the  
 9 Early Show, a CBS morning talk program, “There are 50 million patients in this country who  
 10 have chronic pain that’s not being managed appropriately every single day. OxyContin is one of  
 11 the choices that doctors have available to them to treat that.”<sup>36</sup>

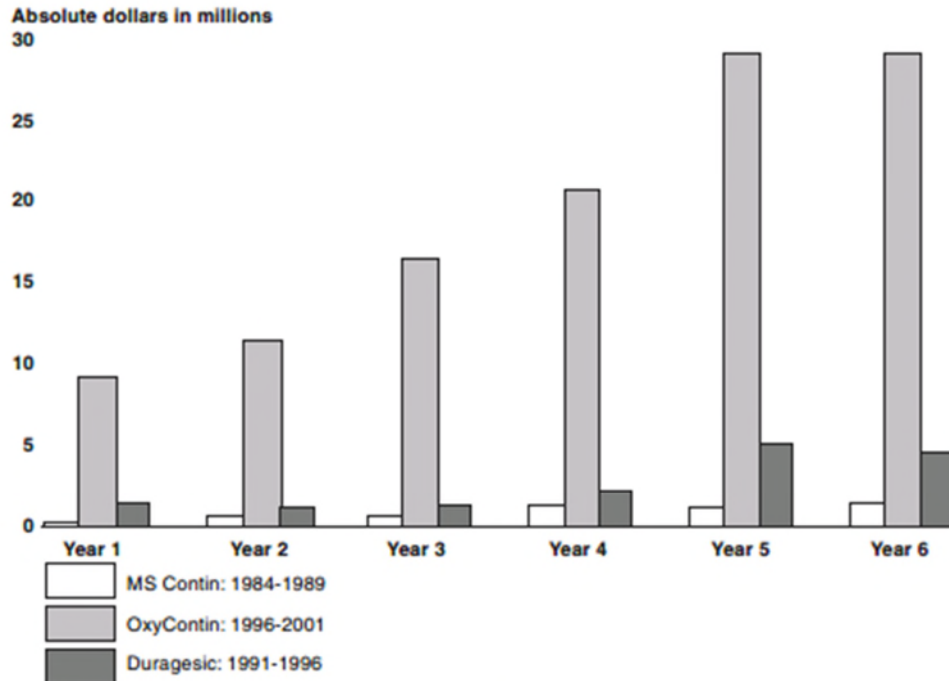
12 138. In pursuit of these 50 million potential customers and Richard Sackler’s “blizzard  
 13 of prescriptions,” Purdue poured resources into OxyContin’s sales force and advertising. As  
 14 shown below, Purdue’s early promotional spending on OxyContin dwarfed spending on MS  
 15 Contin or Defendant Janssen’s spending on Duragesic:<sup>37</sup>

26 <sup>35</sup> MA Complaint ¶ 178.

27 <sup>36</sup> *Id.* at 156.

<sup>37</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. Gen. Acct. Off. Rep. to Cong. Requesters at 22 (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

**Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales**



139. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners. Today, one in every five patients who present themselves to physicians' offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid prescription.<sup>38</sup>

<sup>38</sup> Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Ctrs. for Disease Control and Prevention (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> [hereinafter 2016 CDC Guideline].

**3. Following reports of OxyContin abuse and federal investigations, the Sacklers continued to promote opioids but took steps to shield their assets from judgment.**

140. Purdue's aggressive sales push quickly led to reports of OxyContin abuse and fatal overdoses. Both Purdue as a company and the Sacklers as individuals knew about significant abuse of OxyContin in the first years after the drug's introduction in 1996.<sup>39</sup> In early 1999, Purdue's general counsel, Howard Udell, wrote to another Purdue official that the company had learned of references on the internet to the abuse of Purdue's opioid products.<sup>40</sup> Prosecutors wrote that Richard Sackler was told in 1999 about discussions in internet chatrooms about snorting OxyContin.<sup>41</sup> Richard Sackler's knowledge in the late 1990s of OxyContin's status as a highly sought-after street drug was confirmed in his deposition testimony from earlier litigation, only released to the public in February 2019.<sup>42</sup>

141. Yet at a 2001 congressional hearing on the increase in opioid abuse, Purdue President Michael Friedman testified that Purdue first became aware of the abuse of OxyContin in April 2000, after news reports of people abusing the drug recreationally in Maine.<sup>43</sup> None of the Sacklers attempted to correct this misrepresentation.

142. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, while raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy.

<sup>39</sup> Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, New York Times (May 29, 2018), <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html?login=email&auth=login-email>.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> David Armstrong, *Sackler Embraced Plan to Conceal OxyContin's Strength from Doctors, Sealed Testimony Shows*, ProPublica (Feb. 21, 2019, 1:45pm), <https://www.propublica.org/article/richard-sackler-oxycontin-oxycodone-strength-conceal-from-doctors-sealed-testimony>.

<sup>43</sup> Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

1 The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its  
2 2006 sales of \$800 million.

3 143. In addition, in November 2007, just months after Purdue pleaded guilty for  
4 deceiving patients and doctors, the Sacklers established Rhodes Pharmaceuticals L.P., a  
5 manufacturer of generic opioids, to continue profiting from the epidemic they helped create. This  
6 development expanded the operations of Rhodes Technologies, Inc., which was primarily  
7 involved with manufacture of bulk active pharmaceutical ingredients. The connection between  
8 the Sacklers and Rhodes was not widely known until the publication of a 2018 *Financial Times*  
9 article.<sup>44</sup>

10 144. In public statements responding to the opioid crisis, Purdue has claimed a  
11 minimal role, stating, for example, that OxyContin accounted for only 1.4% of all opioid  
12 analgesic prescriptions written between October 2017 and September 2018.<sup>45</sup> But the Sacklers'  
13 establishment and control of Rhodes Pharmaceuticals L.P. means that the Sacklers are  
14 responsible for a larger market share than that. As *Financial Times* reported, "Rhodes is a much  
15 larger producer of opioids by volume, and the combined companies accounted for 14.4m  
16 prescriptions that year, giving them an overall market share of 6 percent in 2016."<sup>46</sup>

17 145. The Sacklers are beneficial owners of and exercise control over not only Rhodes  
18 Pharmaceuticals L.P., but all four Rhodes entities. The Sacklers thus have profited not only from  
19 Purdue's earnings on excessive prescription opioid sales, but also from the sales of opioids by  
20 multiple additional corporate entities.

21 146. Purdue did little to change policies regarding the promotion of opioids, and the  
22 Sacklers were intimately involved in continuing the misconduct. After the 2007 guilty plea, the  
23 Sacklers directed Purdue to hire hundreds of additional sales representatives.<sup>47</sup> The Sacklers also  
24

25 <sup>44</sup> See David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids*, *Financial Times* (Sept. 9,  
2018), <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>.

26 <sup>45</sup> *Common Myths About OxyContin (oxycodone HCl) Extended-Release Tablets CII, Purdue Pharma*,  
<https://www.purduepharma.com/news-media/common-myths-about-oxycontin/> (last visited Aug. 30, 2109).

27 <sup>46</sup> Crow, *supra* note 44.

<sup>47</sup> NY Complaint ¶ 394.

1 required their sales representatives to average at least 7.5 prescribers daily, as well as having  
2 those prescribers agree to increasing prescriptions.

3 147. Richard Sackler was especially involved in overseeing and directing sales  
4 operations. He personally went into the field, for example, to supervise Purdue's sales  
5 representatives.<sup>48</sup> As a result of his time in the field, he argued with Vice President Russell  
6 Gasdia that legally required warnings about opioids were unnecessary and that a warning  
7 "implies a danger of untoward reactions and hazards that simply aren't there."<sup>49</sup>

8 148. The other Sacklers remained deeply involved in sales as well. In 2012, for  
9 example, Mortimer Sackler suggested Purdue reschedule an annual sales meeting from January  
10 to February so that sales representatives could "get back to work for January and back in front of  
11 doctors who enter the new year refreshed..."<sup>50</sup> Richard Sackler proposed canceling the meeting  
12 entirely.<sup>51</sup>

13 149. Despite the company's outward appearances, the Sacklers recognized that the  
14 increased pressure on the company required loyalty to the family. In 2010, Purdue staff provided  
15 the Sacklers a 10-year plan for Purdue's opioid sales, under which the Sacklers would receive at  
16 least \$700 million per year from 2010 to 2020.<sup>52</sup>

17 150. Purdue proved itself skilled at evading full responsibility and continuing to sell  
18 through the controversy. The company's annual opioid sales of \$3 billion in 2015 represent a  
19 four-fold increase from its 2006 sales of \$800 million.

20 151. Nonetheless, the Sacklers found themselves on the defensive more and more often  
21 after 2010. For example, in late 2017, insurance provider Cigna made public statements about  
22 how opioid companies influence prescribing and dosing.<sup>53</sup> Cigna also replaced OxyContin on its  
23

24 <sup>48</sup> NY Complaint ¶ 393.

25 <sup>49</sup> MA Complaint ¶ 356.

26 <sup>50</sup> NY Complaint ¶ 396.

27 <sup>51</sup> *Id.*

<sup>52</sup> NY Complaint ¶ 420.

<sup>53</sup> See Karen Eldred, *Cigna is Committed to Reducing Opioid Use: Removing Oxycontin from Group Commercial Drug Lists on 1/1/18*, Cigna (Oct. 4, 2017), <https://www.cigna.com/newsroom/news-releases/2017/cigna-is-committed-to-reducing-opioid-use-removing-oxycontin-from-group-commercial-drug-lists-on-1-1-18> ("While drug

list of covered drugs with a competitor's drug. Upon learning this, Richard Sackler suggested Purdue replace Cigna as the insurance provider for Purdue's company health plan.<sup>54</sup>

152. Bowing to increasing pressure and scrutiny, the Sacklers resigned from the Purdue board of directors in 2018.<sup>55</sup>

**4. In response to enforcement actions in the United States, the Sacklers have moved their aggressive opioid marketing—and their wealth—overseas.**

153. Since at least 1999, the Sacklers have known of the high potential for abuse of OxyContin. Rather than take steps to ameliorate the damage they have caused—or to prevent additional harm—the Sacklers instead began to shift profits from Purdue and related entities to their own private trusts and accounts in order to shield them from creditors. The entities to which the Sacklers transferred funds include PLP Associates Holding L.P., Rosebay Medical Company L.P, and Beacon Company. These transfers were and are fraudulent, unjustly enriching the Sacklers and shielding funds available for the execution of any judgment against Purdue.

154. At the time of Purdue's 2007 guilty plea—in which The Purdue Frederick Company, Inc. officially pled guilty—Purdue Pharma L.P. identified a total of 215 “related and associated entities” in its Non-Prosecution Agreement with the United States. These associated entities include, for example, petroleum and real estate companies, and twenty-five entities registered in Bermuda or the British Virgin Islands. The Sacklers—while directing Purdue to push its highly addictive drug into the poorest corners of Appalachia and to target Medicaid patients and veterans—availed themselves of the legal gray area available only to the wealthy, establishing international shell companies to hold and reinvest their profits. Securities filings show, for example, that the Sacklers have directed Purdue to purchase shares in various

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companies don't control prescriptions, they can help influence patient and doctor conversations by educating people about their medications.”).

<sup>54</sup> MA Complaint at ¶ 490.

<sup>55</sup> See Beth Mole, *Damning court docs show just how far Sacklers went to push OxyContin*, ARS Technica (Jan. 19, 2019, 5:00am), <https://arstechnica.com/science/2019/01/family-behind-oxycontin-called-addicts-criminals-while-pushing-pills/>.



1 pharmaceutical investments, and then transferred those shares immediately to Rosebay Medical  
2 Company L.P. and Beacon Company.

3 155. Over the years, the Sacklers have voted to distribute billions of dollars to  
4 themselves through such associated entities. Between 2008 and 2016, the Sacklers voted to  
5 distribute over \$2 billion of Purdue's profits to PLP Associates Holding L.P.<sup>56</sup> The Sacklers also  
6 voted to distribute approximately \$1.8 billion to Rosebay Medical Company L.P. and Beacon  
7 Company between 2008 and 2014.<sup>57</sup>

8 156. Many of the associated entities identified in Purdue's 2007 list of "associated  
9 entities" are part of the Mundipharma network of companies, which was started by the Sacklers  
10 and remains under their control. Mundipharma is integral in allowing the Sacklers to both move  
11 their wealth overseas and continue to profit from the sale of addictive opioids as government  
12 entities in the United States work to rein in opioid prescribing. In contrast to the Sacklers' well-  
13 documented obsession with attaching their family name to art museum wings, endowed chairs at  
14 universities, and the like, the Sacklers have omitted their name from official statements about  
15 Mundipharma's founding. Press release after press release describes the Mundipharma networks  
16 as "founded in 1956 by doctors."<sup>58</sup> Mundipharma International's website provides more detail  
17 (and corrects the date), but still leaves it founders nameless: "Founded in the US by two  
18 physicians in 1952 and still privately owned, the network has a presence in over 120  
19 countries."<sup>59</sup> But the Austrian arm of the network is more forthright:

20 The Austrian company Mundipharma Ges.m.b.H. is part of a privately owned  
21 network of independent associated companies that operates internationally. The  
22 founding history dates back to 1952, when the two brothers Mortimer D. Sackler,  
M.D. and Raymond R. Sackler, M.D. bought the US-based company Purdue.

23 <sup>56</sup> Amended Complaint at ¶ 151, *State of Connecticut v. Purdue Pharma L.P.*, C.A. No. X07 HHD-CV-19-6105325-  
S (Conn. Super. Ct. May 6, 2019) ("CT Complaint").

24 <sup>57</sup> CT Complaint ¶¶ 153-154.

25 <sup>58</sup> See, e.g., *Purdue Pharma L.P. Announces Strategic Investment in Oncology R&D*, Market Watch (Nov. 14,  
2017), <https://www.marketwatch.com/press-release/purdue-pharma-lp-announces-strategic-investment-in-oncology-rd-2017-11-14>; *Mundipharma strengthens position as a leader in biosimilars with acquisition of development company Cinfa Biotech*, Mundipharma (Oct. 2018), <https://www.mundipharma.com/wp-content/uploads/2018/10/201008-Deal-release-FINAL.pdf>.

27 <sup>59</sup> *About Mundipharma*, Mundipharma, <https://www.mundipharma.com/about-mundipharma/> (last visited Aug. 30, 2019).



1 Blessed with the necessary pioneering spirit, the owners developed a network of  
 2 independent associated companies that is currently represented in numerous  
 3 European countries and worldwide. The tradition of a family business has  
 4 propagated over the years and is still reflected, e.g. in long-term and trusting  
 5 relationships.<sup>60</sup>

6 157. As the corporate history webpages of various Mundipharma entities explain, it  
 7 was Mundipharma that developed the prolonged-release morphine sulfate tablet in 1973,<sup>61</sup> which  
 8 was later sold in the U.S. as MS Contin and which would be applied to oxycodone to create  
 9 OxyContin. At that time, “Mundipharma” included Purdue, the UK-based Napp Pharmaceuticals  
 10 Limited, which the Sacklers had acquired in 1966, and Ireland-based Napp Laboratories, which  
 11 developed the fateful timed-release coating in 1973.

12 158. Today, the Mundipharma network generates over \$3.4 billion in annual revenue,  
 13 primarily from opioids.<sup>62</sup> As noted above, Mundipharma is privately owned. Little public  
 14 information is available regarding that ownership. However, the information that is available  
 15 reveals that companies and trusts established by the Sacklers own various parts of the  
 16 Mundipharma network. For example, trusts for the benefit of Richard and Jonathan Sackler  
 17 owned half of Mundipharma Research Ltd. in Cambridge, England.<sup>63</sup> Rosebay Medical  
 18 Company L.P.—owned by trusts for the benefit of the Sacklers—is one of the two owners of  
 19 Mundipharma’s Australian business, according to data from the Australian Securities and  
 20 Investments Commission, and is one of the two current shareholders in Mundipharma  
 21 Pharmaceuticals Sdn. Bhd., the network’s Malaysian branch, according to the Companies  
 22 Commission of Malaysia.<sup>64</sup>

23 <sup>60</sup> History, Mundipharma, <https://mundipharma.at/geschichte/> (last visited Aug. 30, 2019).

24 <sup>61</sup> See, e.g., Mundipharma Malaysia website stating “Mundipharma developed prolonged release technology for  
 25 treating chronic pain” in 1973, Mundipharma, <http://www.mundipharma.com.my/about-us> (last visited Aug. 30,  
 26 2019); History, Mundipharma, <http://www.mundipharma.ie/history> (last visited Aug. 30, 2019).

27 <sup>62</sup> Bruce Einhorn, Timothy Annett, and Tim Loh, *OxyContin Billionaires Chase Global Profits to Offset U.S. Woes*,  
 Bloomberg (March 30, 2019), [https://www.bloomberg.com/news/articles/2019-03-30/oxycotin-billionaires-  
 chase-global-profits-to-offset-u-s-woes](https://www.bloomberg.com/news/articles/2019-03-30/oxycotin-billionaires-chase-global-profits-to-offset-u-s-woes).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

1           159. Under the name of Mundipharma, the Sacklers are employing the exact same  
2           playbook in South America, China, India, and other developing markets as they did in the United  
3           States.

4           160. In May 2017, a dozen members of Congress sent a letter to the World Health  
5           Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world  
6           through Mundipharma:

7           We write to warn the international community of the deceptive and dangerous  
8           practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The  
9           greed and recklessness of one company and its partners helped spark a public health  
10          crisis in the United States that will take generations to fully repair. We urge the  
11          World Health Organization (WHO) to do everything in its power to avoid allowing  
12          the same people to begin a worldwide opioid epidemic. Please learn from our  
13          experience and do not allow Mundipharma to carry on Purdue’s deadly legacy on  
14          a global stage. . .

15          Internal documents revealed in court proceedings now tell us that since the early  
16          development of OxyContin, Purdue was aware of the high risk of addiction it  
17          carried. Combined with the misleading and aggressive marketing of the drug by its  
18          partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated  
19          American communities since the end of the 1990s. Today, Mundipharma is using  
20          many of the same deceptive and reckless practices to sell OxyContin abroad. . .

21          In response to the growing scrutiny and diminished U.S. sales, the Sacklers have  
22          simply moved on. On December 18, the Los Angeles Times published an extremely  
23          troubling report detailing how in spite of the scores of lawsuits against Purdue for  
24          its role in the U.S. opioid crisis, and tens of thousands of overdose deaths,  
25          Mundipharma now aggressively markets OxyContin internationally. In fact,  
26          Mundipharma uses many of the same tactics that caused the opioid epidemic to  
27          flourish in the U.S., though now in countries with far fewer resources to devote to  
28          the fallout.<sup>65</sup>

29          161. The Sacklers’ pivot to untapped markets, after extracting substantial profits from  
30          communities like Spokane and leaving the City to address the resulting damage, underscores that  
31          their actions have been knowing, intentional, and motivated by profits throughout this entire  
32          tragic story.

<sup>65</sup> Letter from Cong. of the U.S., to Dr. Margaret Chan, Dir.-Gen., World Health Org. (May 3, 2017),  
<https://web.archive.org/web/20181222034138/https://katherineclark.house.gov/cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf>.

**C. The Booming Business of Addiction.**

**1. Other Manufacturing Defendants leapt at the opioid opportunity.**

162. Purdue created a market in which the prescription of powerful opioids for a range of common aches and pains was not only acceptable but encouraged—but it was not alone. Defendants Endo, Janssen, Mallinckrodt, Teva, and Actavis positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin while misrepresenting the safety and efficacy of their products. In addition, Rhodes manufactured multiple generic opioids, profiting from the same misleading marketing and expanded market for these dangerous drugs.

163. Endo, which for decades had sold Percocet and Percodan, both containing relatively low doses of oxycodone, moved quickly to develop a generic version of extended-release oxycodone to compete with OxyContin, receiving tentative FDA approval for its generic version in 2002. As Endo stated in its 2003 Form 10-K, it was the first to file an application with the FDA for bioequivalent versions of the 10, 20, and 40 mg strengths of OxyContin, which potentially entitled it to 180 days of generic marketing exclusivity—“a significant advantage.”<sup>66</sup> Purdue responded by suing Endo for patent infringement, litigating its claims through a full trial and a Federal Circuit appeal—unsuccessfully. As the trial court found, and the appellate court affirmed, Purdue obtained the oxycodone patents it was fighting to enforce through “inequitable conduct”—namely, suggesting that its patent applications were supported by clinical data when in fact they were based on an employee’s “insight and not scientific proof.”<sup>67</sup> Endo began selling its generic extended-release oxycodone in 2005.

164. At the same time as Endo was battling Purdue over generic OxyContin—and as the U.S. was battling increasingly widespread opioid abuse—Endo was working on getting another branded prescription opioid on the market. In 2002, Endo submitted applications to the

<sup>66</sup> *Endo Pharm. Holdings, Inc. Form 10-K*, U.S. Sec. and Exchange Comm’n, at 4 (Mar. 15, 2004), [http://media.corporate-ir.net/media\\_files/irol/12/123046/reports/10K\\_123103.pdf](http://media.corporate-ir.net/media_files/irol/12/123046/reports/10K_123103.pdf).

<sup>67</sup> *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).

1 FDA for both immediate-release and extended-release tablets of oxymorphone, branded as  
2 Opana and Opana ER.

3 165. Like oxycodone, oxymorphone is not a new drug; it was first synthesized in  
4 Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name  
5 Numorphan, in injectable, suppository, and oral tablet forms. But the oral tablets proved highly  
6 susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills, Numorphan  
7 provoked, according to some users, a more euphoric high than heroin, and even had its moment  
8 in the limelight as the focus of the movie *Drugstore Cowboy*. As the National Institute on Drug  
9 Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely  
10 popular among addicts for its quick and sustained effect.<sup>68</sup> Endo withdrew oral Numorphan from  
11 the market in 1979, reportedly for “commercial reasons.”<sup>69</sup>

12 166. Two decades later, however, as communities around the U.S. were first sounding  
13 the alarm about prescription opioids and Purdue executives were being called to testify before  
14 Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted  
15 off a product it had previously shelved after widespread abuse, and pushed it into the  
16 marketplace with a new trade name and a potent extended-release formulation.

17 167. The clinical trials submitted with Endo’s first application for approval of Opana  
18 were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be  
19 revived with naloxone, an opioid antagonist used to counter the effects of an overdose. Endo  
20 then submitted new “enriched enrollment” clinical trials, in which trial subjects who do not  
21 respond to the drug are excluded from the trial, and obtained approval. Endo began marketing  
22 Opana and Opana ER in 2006.

23 168. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017,  
24 the FDA sought removal of Opana ER. In its press release, the FDA indicated that “the agency is  
25 seeking removal based on its concern that the benefits of the drug may no longer outweigh its

26 <sup>68</sup> John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015),  
27 <https://www.medpagetoday.com/psychiatry/addictions/51448>.

<sup>69</sup> *Id.*

1 risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain  
 2 medication from sale due to the public health consequences of abuse.”<sup>70</sup> On July 6, 2017, Endo  
 3 agreed to withdraw Opana ER from the market.<sup>71</sup> Before its withdrawal from the market, Opana  
 4 ER generated substantial profits for Endo—more than \$1 billion in revenue in 2010, for example,  
 5 and again in 2013.

6 169. Janssen, which already marketed the Duragesic (fentanyl) patch, developed a new  
 7 opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate  
 8 to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of  
 9 chronic pain in 2011. Janssen earned more than \$1 billion in sales of Duragesic in 2009, and  
 10 Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

11 170. Teva also manufactures Actiq, a fentanyl lozenge, and Fentora, a fentanyl tablet.  
 12 As noted above, fentanyl is an extremely powerful synthetic opioid. According to the DEA, as  
 13 little as two milligrams is a lethal dosage for most people. Actiq has been approved by the FDA  
 14 only for the “management of breakthrough cancer pain in patients 16 years and older with  
 15 malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy  
 16 for the underlying persistent cancer pain.”<sup>72</sup> Fentora has been approved by the FDA only for the  
 17 “management of breakthrough pain in cancer patients 18 years of age and older who are already  
 18 receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent  
 19 cancer pain.”<sup>73</sup>

20 171. In 2008, Teva subsidiary Cephalon pled guilty to a criminal violation of the  
 21 Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs  
 22 and agreed to pay \$425 million.

23  
 24 <sup>70</sup> Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse*  
 (June 8, 2017), [https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-  
 related-abuse](https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse).

25 <sup>71</sup> *Endo pulls opioid as U.S. seeks to tackle abuse epidemic*, Reuters (July 6, 2017, 9:59am),  
 26 <https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II>.

<sup>72</sup> *Prescribing Information, ACTIQ®*, U.S. Food & Drug Admin.,  
 27 [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020747s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf) (last visited Aug. 30, 2019).

<sup>73</sup> *Prescribing Information, FENTORA®*, U.S. Food & Drug Admin.,  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/021947s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf) (last visited Aug. 30, 2019).

1           172. Actavis acquired the rights to Kadian, extended-release morphine, in 2008, and  
2 began marketing Kadian in 2009. Actavis's opioid products also include Norco, a brand-name  
3 hydrocodone and acetaminophen pill, first approved in 1997. But Actavis, primarily a generic  
4 drug maker, pursued opioid profits through generics, selling generic versions of OxyContin,  
5 Opana, and Duragesic. In 2013, it settled a patent lawsuit with Purdue over its generic version of  
6 "abuse-deterrent" OxyContin, striking a deal that would allow it to market its abuse-deterrent  
7 oxycodone formulation beginning in 2014. Actavis anticipated over \$100 million in gross profit  
8 from generic OxyContin sales in 2014 and 2015.

9           173. Mallinckrodt's generic oxycodone achieved enough market saturation to have  
10 several street names: "M's," based on the imprint on the pills, "blues" because of the pale blue  
11 color of the pills, "roxies," or "mallies." Mallinckrodt's oxy 30s were extremely popular pills for  
12 misuse and abuse, and enormous quantities of Mallinckrodt's pills went to cash purchases and  
13 non-medical use. As noted above, Mallinckrodt was the subject of a federal investigation based  
14 on diversion of its oxycodone in Florida, where 500 million of its pills were shipped between  
15 2008 and 2012. Federal prosecutors alleged that 43,991 orders from distributors and retailers  
16 were excessive enough to be considered suspicious and should have been reported to the DEA.

17           174. Mallinckrodt also pursued a share of the branded opioid market. In 2007,  
18 Mallinckrodt launched Magnacet, an oxycodone and acetaminophen combination pill. In 2008,  
19 Mallinckrodt (then Covidien) launched TussiCaps, a hydrocodone and chlorpheniramine capsule,  
20 marketed as a cough suppressant. And in 2009, Mallinckrodt acquired the U.S. rights to Exalgo,  
21 a potent extended-release hydromorphone tablet, and began marketing it in 2012. Mallinckrodt  
22 further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne  
23 Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release  
24 combination of oxycodone and acetaminophen, which the FDA approved in March 2014. In  
25 anticipation of Xartemis XR's approval, Mallinckrodt hired approximately 200 sales  
26  
27

1 representatives to promote it, and CEO Mark Trudeau said the drug could generate “hundreds of  
2 millions in revenue.”<sup>74</sup>

3 175. These companies’ aggressive promotion of their branded opioids dramatically  
4 expanded the market for these potent and addictive drugs as a class—and much of the demand  
5 was filled by generic opioids. Defendants Mallinckrodt, Actavis, Endo, and Teva all sold generic  
6 opioids in addition to their branded products. Purdue and the Sacklers were also in the generic  
7 business through Rhodes. These Defendants manufactured and shipped massive quantities of  
8 generic opioids to communities across the U.S., including Plaintiff’s, while failing to uphold  
9 their responsibilities to monitor and report suspicious orders.

10 176. All told, the Manufacturing Defendants have reaped enormous profits from the  
11 addiction crisis they spawned.

12 **2. Distributor Defendants knowingly supplied dangerous quantities of opioids**  
13 **while advocating for limited oversight and enforcement.**

14 177. The Distributor Defendants track and keep a variety of information about the  
15 pharmacies and other entities to which they sell pharmaceuticals. For example, the Distributor  
16 Defendants use “know your customer” questionnaires that track the number and types of pills  
17 their customers sell, absolute and relative amounts of controlled substances they sell, whether the  
18 customer purchases from other distributors, and types of medical providers in the areas, among  
19 other information.

20 178. These questionnaires and other sources of information available to the Distributor  
21 Defendants provide ample data to put the Distributor Defendants on notice of suspicious orders,  
22 pharmacies, and doctors.

23 179. Nevertheless, the Distributor Defendants refused or failed to identify, investigate,  
24 or report suspicious orders of opioids to the DEA. Even when the Distributor Defendants had  
25

26  
27 <sup>74</sup> Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Bus. Journal (Dec. 30, 2013),  
<http://argencapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.



1 actual knowledge that they were distributing opioids to drug diversion rings, they refused or  
2 failed to report these sales to the DEA.

3 180. By not reporting suspicious opioid orders or known diversions of prescription  
4 opioids, not only were the Defendants able to continue to sell opioids to questionable customers,  
5 Defendants ensured that the DEA had no basis for decreasing or refusing to increase production  
6 quotas for prescription opioids.

7 181. The Distributor Defendants collaborated with each other and with the  
8 Manufacturing Defendants to maintain distribution of excessive amounts of opioids. One  
9 example of this collaboration came to light through Defendants' work in support of legislation  
10 called the Ensuring Patient Access and Effective Drug Enforcement (EPAEDE) Act, which was  
11 signed into law in 2016 and limited the DEA's ability to stop the flow of opioids. Prior to this  
12 law, the DEA could use an "immediate suspension order" to halt suspicious shipments of pills  
13 that posed an "imminent" threat to the public. The EPAEDE Act changed the required showing  
14 to an "immediate" threat—an impossible standard given the fact that the drugs may sit on a shelf  
15 for a few days after shipment. The law effectively neutralized the DEA's ability to bring  
16 enforcement actions against distributors.

17 182. The legislation was drafted by a former DEA lawyer, D. Linden Barber, who is  
18 now a senior vice president at Defendant Cardinal Health. Prior to leaving the DEA, Barber had  
19 worked with Joseph Rannazzisi, then the chief of the DEA's Office of Diversion Control, to plan  
20 the DEA's fight against the diversion of prescription drugs. So when Barber began working for  
21 Cardinal Health, he knew just how to neutralize the effectiveness of the DEA's enforcement  
22 actions. Barber and other promoters of the EPAEDE Act portrayed the legislation as maintaining  
23 patient access to medication critical for pain relief. In a 2014 hearing on the bill, Barber testified  
24 about the "unintended consequences in the supply chain" of the DEA's enforcement actions. But  
25 by that time, communities across the United States, including Plaintiff City of Spokane, were  
26 grappling with the "unintended consequences" of Defendants' reckless promotion and  
27 distribution of narcotics.



183. Despite egregious examples of drug diversion from around the country, the promoters of the EPAEDE Act were successful in characterizing the bill as supporting patients' rights. One of the groups supporting this legislation was the Alliance for Patient Access, a "front group" as discussed further below, which purports to advocate for patients' rights to have access to medicines, and whose 2017 list of "associate members and financial supporters" included Defendants Endo, Johnson & Johnson, Actavis, Mallinckrodt, and Teva. In a 2013 "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse," the Alliance for Patient Access asserted multiple "unintended consequences" of regulating pain medication, including a decline in prescriptions as physicians feel burdened by regulations and stigmatized.<sup>75</sup>

184. The Distributor Defendants are also part of the activities of the Alliance for Patient Access, although their involvement is hidden. One example of their involvement was revealed by the metadata of an electronic document: the letter from the Alliance for Patient Access in support of the EPAEDE Act. That document was created by Kristen Freitas, a registered lobbyist and the vice president for federal government affairs of the Healthcare Distributors Alliance (HDA)—the trade group that represents Defendants McKesson, Cardinal Health, and AmerisourceBergen.

185. Upon information and belief, the collaboration on the EPAEDE Act is just one example of how the Manufacturing Defendants and the Distributor Defendants, through third-party "front groups" like the Alliance for Patient Access and trade organizations like HDA, worked together behind the scenes to ensure that the flow of dangerous narcotics into communities across the country would not be restricted, and Defendants collaborated in other ways that remain hidden from public view.

186. Another example of collaboration between the Manufacturing Defendants, Distributor Defendants, and Front Groups is the Pain Care Forum, a coalition of drug makers,

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<sup>75</sup> *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Inst. for Patient Access (Oct. 2013), [http://1yh21u3cjpgt3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT\\_White-Paper\\_Finala.pdf](http://1yh21u3cjpgt3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf).

1 trade groups and non-profit organizations supported by funding from the pharmaceutical  
 2 industry. The Pain Care Forum worked behind the scenes to shape federal and state policies  
 3 regarding the use of prescription opioids, working to prevent national, state, or local responses to  
 4 the growing opioid crisis from interrupting industry profits. The Manufacturing Defendants  
 5 worked together through the Pain Care Forum, and the Distributor Defendants actively  
 6 participated in the Pain Care Forum through the HDA as well.

7 187. The Distributor Defendants have been the subject of numerous enforcement  
 8 actions by the DEA. In 2008, for example, McKesson was fined \$13.3 million and agreed to  
 9 strengthen its controls by implementing a three-tiered system that would flag buyers who  
 10 exceeded monthly thresholds for opioids. As the opioid crisis deepened, the DEA's Office of  
 11 Diversion Control, led by Rannazzisi, stepped up enforcement, filing 52 immediate suspension  
 12 orders against suppliers and pill mills in 2010 alone. Defendant Cardinal Health was fined \$34  
 13 million by the DEA in 2013 for failing to report suspicious orders.

14 188. The Distributor Defendants were not simply passive transporters of opioids. They  
 15 intentionally failed to report suspicious orders and actively pushed back against efforts to enforce  
 16 the law and restrict the flow of opioids into communities like Spokane.

17 **3. Pill mills and overprescribing doctors also placed their financial interests**  
 18 **ahead of their patients' interests.**

19 189. Prescription opioid manufacturers and distributors were not the only ones to  
 20 recognize an economic opportunity. Around the country, including in Spokane, certain doctors or  
 21 pain clinics ended up doing brisk business dispensing opioid prescriptions. As Dr. Andrew  
 22 Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, observed, this business  
 23 model meant doctors would "have a practice of patients who'll never miss an appointment and  
 24 who pay in cash."<sup>76</sup>

25 190. Moreover, the Manufacturing Defendants' sales incentives rewarded sales  
 26 representatives who happened to have pill mills within their territories, enticing those

27 <sup>76</sup> Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* 314 (Bloomsbury Press 2015).

representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting enormous quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions. Eventually, the DEA's diversion unit raided the clinic, and prosecutors filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.<sup>77</sup> In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."<sup>78</sup>

191. Another pill mill, this one in Los Angeles, supplied OxyContin to a drug dealer in Everett, Washington. Purdue was alerted to the existence of this pill mill by one of its regional sales managers, who in 2009 reported to her supervisors that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this was an organized drug ring[.]" She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report." This clinic was the source of 1.1 million pills trafficked to Everett, which is a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.<sup>79</sup> Similarly, Purdue received repeated reports in 2008 from a sales representative who visited a family practice doctor in Bothell, Washington; the sales representative informed Purdue that many of this doctor's patients were men in their twenties

<sup>77</sup> Meier, *supra* note 15, at 298-300.

<sup>78</sup> *Id.*

<sup>79</sup> Harriet Ryan, Scott Glover, and Lisa Girion, *How black-market OxyContin spurred a town's descent into crime, addiction and heartbreak*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-everett/>; Harriet Ryan, Lisa Girion, and Scott Glover, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

1 who did not appear to be in pain, who sported diamond studs and \$350 sneakers, and who always  
2 paid for their 80 mg OxyContin prescriptions in cash. Despite being repeatedly alerted to the  
3 doctor's conduct, Purdue did not take any action to report it until three years later.

4 192. Whenever examples of opioid diversion and abuse have drawn media attention,  
5 the Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001,  
6 during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions  
7 about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but  
8 not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard  
9 Paolino. Udell asserted that Purdue was "fooled" by the "bad actor" doctor: "The picture that is  
10 painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon  
11 this community, who caused untold suffering. And he fooled us all. He fooled law enforcement.  
12 He fooled the DEA. He fooled local law enforcement. He fooled us."<sup>80</sup>

13 193. But given the closeness with which all Defendants monitored prescribing patterns,  
14 including through IMS Health data, it is highly improbable that they were "fooled." In fact, a  
15 local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and  
16 alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Rather, it  
17 appears Purdue and other Defendants used the IMS Health data to target pill mills and sell more  
18 pills. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold  
19 mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

20 194. In addition, the Manufacturing Defendants had the ability to know who the  
21 ultimate customers of their pills were due to their control of "chargeback" data. Chargebacks are  
22 available when distributors purchase the drugs at an established wholesale price, but then sell the  
23 drugs at a discounted price based on contract pricing the Manufacturing Defendants have offered  
24 to the indirect customers. The distributor honors the contract pricing but then submits a  
25 chargeback request to the manufacturer to recover the difference. In order to get the chargeback,  
26 distributors must provide detailed information about the indirect customer and about the product

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27 <sup>80</sup> Meier, *supra* note 15 at 179.

1 sold. As a result, Manufacturing Defendants are collecting data on the indirect customers of their  
 2 products and know exactly how many of their pills are going where. And like the Distributor  
 3 Defendants, Manufacturing Defendants are also subject to the monitoring and reporting  
 4 requirements of the CSA.

5 195. The Manufacturing Defendants tracked their pills through chargeback and IMS  
 6 data and/or received reports from sales representatives making in-person visits. They had the  
 7 ability, and the obligation, to monitor and report suspicious orders. But pill mills were highly  
 8 lucrative. Defendants knowingly allowed certain clinics to dispense staggering quantities of  
 9 potent opioids and then feigned surprise when the most egregious examples eventually made the  
 10 nightly news.

11 **4. Widespread prescription opioid use broadened the market for heroin and**  
 12 **fentanyl.**

13 196. Defendants' scheme achieved a dramatic expansion of the U.S. market for  
 14 opioids, prescription and non-prescription alike. Heroin and fentanyl use has surged—a  
 15 foreseeable consequence of Defendants' successful promotion of opioid use coupled with the  
 16 sheer potency of their products.

17 197. In his book *Dreamland: The True Tale of America's Opiate Epidemic*, journalist  
 18 Sam Quinones summarized the easy entrance of black tar heroin in a market primed by  
 19 prescription opioids:

20 His black tar, once it came to an area where OxyContin had already tenderized the  
 21 terrain, sold not to tapped-out junkies but to younger kids, many from the suburbs,  
 22 most of whom had money and all of whom were white. Their transition from Oxy  
 23 to heroin, he saw, was a natural and easy one. Oxy addicts began by sucking on and  
 24 dissolving the pills' timed-release coating. They were left with 40 or 80 mg of pure  
 25 oxycodone. At first, addicts crushed the pills and snorted the powder. As their  
 26 tolerance built, they used more. To get a bigger bang from the pill, they liquefied it  
 27 and injected it. But their tolerance never stopped climbing. OxyContin sold on the  
 street for a dollar a milligram and addicts very quickly were using well over 100

mg a day. As they reached their financial limits, many switched to heroin, since they were already shooting up Oxy and had lost any fear of the needle.<sup>81</sup>

198. In a study examining the relationship between the abuse of prescription opioids and heroin, researchers found that 75% of those who began their opioid abuse in the 2000s reported that their first opioid was a prescription drug.<sup>82</sup> As the graph below illustrates, prescription opioids replaced heroin as the first opioid of abuse beginning in the 1990s.



From: **The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years**

JAMA Psychiatry. 2014;71(7):821-826. doi:10.1001/jamapsychiatry.2014.366

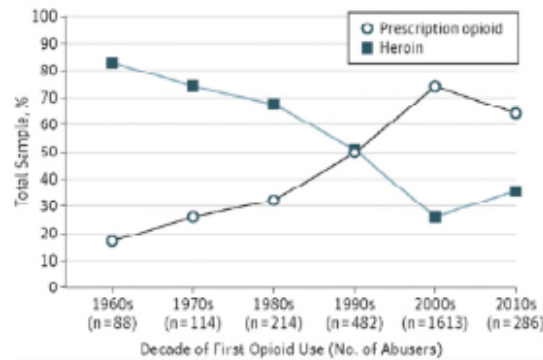


Figure Legend:

Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of Abuse Data are plotted as a function of the decade in which respondents initiated their opioid abuse.

199. The researchers also found that nearly half of the respondents who indicated that their primary drug was heroin actually preferred prescription opioids, because the prescription drugs were legal, and perceived as “safer and cleaner.” But, heroin’s lower price point is a distinct advantage. While an 80 mg OxyContin might cost \$80 on the street, the same high can be had from \$20 worth of heroin.

<sup>81</sup> Quinones, *supra* note 76, at 165-66.

<sup>82</sup> Theodore J. Cicero, PhD, Matthew S. Ellis, MPE, Hilary L. Surratt, PhD, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71(7) JAMA Psychiatry 821-826 (2014), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

200. As noted above, there is little difference between the chemical structures of heroin and prescription opioids. Between 2005 and 2009, Mexican heroin production increased by over 600%. And between 2010 and 2014, the amount of heroin seized at the U.S.-Mexico border more than doubled.

201. From 2000 to 2017, fatal overdoses related to heroin in the U.S. increased by 766%—from 1,842 deaths in 2000 to 15,958 deaths in 2017.<sup>83</sup>

202. Along with heroin use, fentanyl use is on the rise, as a result of America's expanded appetite for opioids. But fentanyl, as noted above, is fifty times more potent than heroin, and overdosing is all too easy. In 2013, fentanyl caused 3,000 overdose deaths. By 2017, the number of deaths attributed to the potent synthetic opioid had risen to 29,000. Deaths involving fentanyl increased more than 45 percent in 2017 alone.<sup>84</sup>

203. As Dr. Caleb Banta-Green, senior research scientist at the University of Washington's Alcohol and Drug Abuse Institute, told The Seattle Times in August 2017, "The bottom line is opioid addiction is the overall driver of deaths. People will use whatever opioid they can get. It's just that which one they're buying is changing a bit."<sup>85</sup>

204. In addition to the expanded market for opioids of all kinds, the opioid epidemic has contributed to a resurgence in methamphetamine use, as some opioid users turn to the stimulant to counter the effects of opioids.<sup>86</sup> Co-use of methamphetamine and opioids has nearly doubled in the last six years. From 2011 to 2017, the percentage of opioid users seeking treatment who reported also using methamphetamine in the prior month jumped from 19% to

<sup>83</sup> *Overdose Death Rates*, *supra* note 4.

<sup>84</sup> Josh Katz and Margot Sanger-Katz, 'The Numbers Are So Staggering.' *Overdose Deaths Set a Record Last Year*, The New York Times (Nov. 29, 2018), <https://www.nytimes.com/interactive/2018/11/29/upshot/fentanyl-drug-overdose-deaths.html>.

<sup>85</sup> *Opioids: The Leading Cause of Drug Deaths in Seattle Area*, U. of Wash. Sch. of Pub. Health (Aug. 25, 2017), <https://sph.washington.edu/news-events/news/opioids-leading-cause-drug-deaths-seattle-area>.

<sup>86</sup> See, e.g., *Opioids and methamphetamine: a tale of two crises*, 391(10122) The Lancet 713 (Feb. 24, 2018), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30319-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30319-2/fulltext); Brenda Goodman, MA, *Experts Warn of Emerging 'Stimulant Epidemic'*, WebMD (Apr. 3, 2018), <https://www.webmd.com/mental-health/addiction/news/20180403/experts-warn-of-emerging-stimulant-epidemic>.



34%.<sup>87</sup> This increase in co-use did not occur with any other drug class.<sup>88</sup> The two drugs' opposite modes of action balance each other out, making co-use appealing to opioid users who need to be active at certain times. As one article explained, "[f]or addicts, the drugs pair: Heroin is a downer and methamphetamine is an upper."<sup>89</sup> Researchers studying the "twin epidemics" have found that some opioid users will turn to methamphetamine as a substitute to opioids to stave off withdrawals if they cannot obtain opioids.<sup>90</sup> And as opioids become more difficult to obtain and afford, users increasingly turn to cheap methamphetamine.<sup>91</sup> Co-use of opioids and methamphetamines is rising around the United States, compounding the issues that local governments face in combating the opioid epidemic.<sup>92</sup>

#### **D. The Marketing Defendants Promoted Prescription Opioids Through Several Channels.**

205. Despite knowing the devastating consequences of widespread opioid use, the Marketing Defendants engaged in a sophisticated and multi-pronged promotional campaign designed to achieve just that. By implementing the strategies pioneered by Arthur Sackler, these Defendants were able to achieve the fundamental shift in the perception of opioids that was key to making them blockbuster drugs.

206. The Marketing Defendants disseminated their deceptive statements about opioids through several channels.<sup>93</sup> First, these Defendants aggressively and persistently pushed opioids through sales representatives. Second, these Defendants funded third-party organizations that appeared to be neutral, but in fact served as additional marketing departments for drug

<sup>87</sup> Matthew Ellis, Zachary Kasper, Theodore Cicero, *Twin epidemics: The surging rise of methamphetamine use in chronic opioid users*, 193 Drug and Alcohol Depend. 14 (Dec. 2018), <https://doi.org/10.1016/j.drugalcdep.2018.08.029>.

<sup>88</sup> *Id.*

<sup>89</sup> Michelle Theriault Boots, *The silent fallout of the opioid epidemic? Meth.*, Anchorage Daily News (Mar. 30, 2018), <https://www.adn.com/alaska-news/2018/03/19/the-silent-fallout-of-the-opioid-epidemic-meth/#>.

<sup>90</sup> Randy Dottinga, *Methamphetamine use climbing among opioid users*, Clinical Psychology News (June 29, 2018), <https://www.medge.com/psychiatry/article/169254/addiction-medicine/methamphetamine-use-climbing-among-opioid-users>.

<sup>91</sup> Rachel Martin, *In Rural Ohio, An Opioid Crisis Becomes A Meth Crisis*, NPR (June 6, 2018, 5:11am), <https://www.npr.org/2018/06/06/617422943/in-rural-ohio-an-opioid-crisis-becomes-a-meth-crisis>.

<sup>92</sup> Ellis, *supra* note 87.

<sup>93</sup> The specific misrepresentations and omissions are discussed below in Section E.



1 companies. Third, these Defendants utilized prominent physicians as paid spokespeople—“Key  
 2 Opinion Leaders”—to take advantage of doctors’ respect for and reliance on the  
 3 recommendations of their peers. Finally, these Defendants also used print and online advertising,  
 4 including unbranded advertising, which is not reviewed by the FDA.

5 207. The Marketing Defendants spent substantial sums and resources in making these  
 6 communications. For example, Purdue spent more than \$200 million marketing OxyContin in  
 7 2001 alone.<sup>94</sup>

8 **1. The Marketing Defendants aggressively deployed sales representatives to**  
 9 **push their products.**

10 208. The Marketing Defendants communicated to prescribers directly in the form of  
 11 in-person visits and communications from sales representatives. The Marketing Defendants’  
 12 sales representatives provided health care providers with pamphlets, visual aids, and other  
 13 marketing materials designed to increase the rate of opioids prescribed to patients. These sales  
 14 representatives knew the doctors they visited relied on the information they provided, and that  
 15 the doctors had minimal time or resources to investigate the materials’ veracity independently.

16 209. The Marketing Defendants’ tactics through their sales representatives—also  
 17 known as “detailers”—were particularly aggressive. In 2014, the Marketing Defendants  
 18 collectively spent well over \$100 million on detailing branded opioids to doctors.

19 210. Each sales representative has a specific sales territory and is responsible for  
 20 developing a list of about 105 to 140 physicians to call on who already prescribe opioids or who  
 21 are candidates for prescribing opioids.

22 211. When Purdue launched OxyContin in 1996, its 300-plus sales force had a total  
 23 physician call list of approximately 33,400 to 44,500. By 2000, nearly 700 representatives had a  
 24 total call list of approximately 70,500 to 94,000 physicians. Each sales representative was  
 25 expected to make about thirty-five physician visits per week and typically called on each

26 <sup>94</sup> *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*,  
 27 107th Cong. 2 (Feb. 12, 2002) (testimony of Paul Goldenheim, Vice President for Research, Purdue Pharma),  
<https://www.gpo.gov/fdsys/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>.

1 physician every three to four weeks, while each hospital sales representative was expected to  
2 make about fifty physician visits per week and call on each facility every four weeks.<sup>95</sup>

3 212. One of Purdue's early training memos compared doctor visits to "firing at a  
4 target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim  
5 and what you want to hit!"<sup>96</sup> According to the memo, the target is physician resistance based on  
6 concern about addiction: "The physician wants pain relief for these patients without addicting  
7 them to an opioid."<sup>97</sup>

8 213. Former sales representative Steven May, who worked for Purdue from 1999 to  
9 2005, explained to a journalist that the most common objection he heard about prescribing  
10 OxyContin was that "it's just too addictive."<sup>98</sup> In order to overcome that objection and hit their  
11 "target," May and other sales representatives were taught to say, "The delivery system is  
12 believed to reduce the abuse liability of the drug."<sup>99</sup> May repeated that line to doctors even  
13 though he "found out pretty fast that it wasn't true."<sup>100</sup> He and his coworkers learned quickly that  
14 people were figuring out how to remove the time-releasing coating, but they continued making  
15 this misrepresentation until Purdue was forced to remove it from the drug's label.

16 214. Purdue trained its sales representatives to misrepresent the addiction risk in other  
17 ways. May explained that he and his coworkers were trained to "refocus" doctors on "legitimate"  
18 pain patients, and to represent that "legitimate" patients would not become addicted. In addition,  
19 they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-  
20 forming" than painkillers that need to be taken every four hours. Similarly, former Purdue sales  
21  
22  
23

<sup>95</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 37, at 20.

<sup>96</sup> Meier, *supra* note 15, at 102.

<sup>97</sup> *Id.*

<sup>98</sup> David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *New Yorker* (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

<sup>99</sup> Keefe, *supra* note 43; see also Meier, *supra* note 15, at 102 ("Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of the drug.").

<sup>100</sup> Keefe, *supra* note 43.

1 manager William Gergely told a Florida state investigator in 2002 that sales representatives were  
2 instructed to say that OxyContin was “virtually non-addicting” and “non-habit-forming.”<sup>101</sup>

3 215. As Shelby Sherman, a Purdue sales representative from 1974 to 1998, told a  
4 reporter regarding OxyContin promotion, “It was sell, sell, sell. We were directed to lie. Why  
5 mince words about it?”<sup>102</sup>

6 216. The Marketing Defendants utilized lucrative bonus systems to encourage their  
7 sales representatives to stick to the script and increase opioid sales in their territories. Purdue  
8 paid \$40 million in sales incentive bonuses to its sales representatives in 2001 alone, with annual  
9 bonuses ranging from \$15,000 to nearly \$240,000.<sup>103</sup> The training memo described above, in  
10 keeping with a Wizard of Oz theme, reminded sales representatives: “A pot of gold awaits you  
11 ‘Over the Rainbow’!”<sup>104</sup>

12 217. As noted above, these Defendants have also spent substantial sums to purchase,  
13 manipulate, and analyze prescription data available from IMS Health, which allows them to track  
14 initial prescribing and refill practices by individual doctors, and in turn to customize their  
15 communications with each doctor. The Marketing Defendants’ use of this marketing data was a  
16 cornerstone of their marketing plan,<sup>105</sup> and continues to this day.

17 218. The Marketing Defendants also aggressively pursued family doctors and primary  
18 care physicians perceived to be susceptible to their marketing campaigns. The Marketing  
19 Defendants knew that these doctors relied on information provided by pharmaceutical companies  
20 when prescribing opioids, and that, as general practice doctors seeing a high volume of patients  
21 on a daily basis, they would be less likely to scrutinize the companies’ claims.

24 <sup>101</sup> Fred Schulte and Nancy McVicar, *Oxycontin Was Touted As Virtually Nonaddictive, Newly Released State*  
25 *Records Show*, Sun Sentinel (Mar. 6, 2003), [http://articles.sun-sentinel.com/2003-03-06/news/0303051301\\_1\\_purdue-pharma-oxycontin-william-gergely](http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely).

26 <sup>102</sup> Glazek, *supra* note 26.

27 <sup>103</sup> Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*,  
99(2) Am J Public Health 221-27 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

<sup>104</sup> Meier, *supra* note 15, at 103.

<sup>105</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 103.

219. Furthermore, the Marketing Defendants knew or should have known the doctors they targeted were often poorly equipped to treat or manage pain comprehensively, as they often had limited resources or time to address behavioral or cognitive aspects of pain treatment or to conduct the necessary research themselves to determine whether opioids were as beneficial as these Defendants claimed. In fact, the majority of doctors and dentists who prescribe opioids are not pain specialists. For example, a 2014 study conducted by pharmacy benefit manager Express Scripts reviewing narcotic prescription data from 2011 to 2012 concluded that of the more than 500,000 prescribers of opioids during that time period, *only* 385 were identified as pain specialists.<sup>106</sup>

220. When the Marketing Defendants presented these doctors with sophisticated marketing material and apparently scientific articles that touted opioids' ability to easily and safely treat pain, many of these doctors began to view opioids as an efficient and effective way to treat their patients.

221. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative in Florida wrote about working for a particularly driven regional manager named Chris Sposato and described how Sposato would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Miami District reps have told me that on work sessions with [Sposato] they would sit in the car and role play for as long as it took until [Sposato] was convinced the rep was delivering the message with perfection.

<sup>106</sup> *A Nation in Pain*, Express Scripts (Dec. 9, 2014), <http://lab.express-scripts.com/lab/publications/a-nation-in-pain>.

1           222. The Marketing Defendants used not only incentives but competitive pressure to  
 2 push sales representatives into increasingly aggressive promotion. One Purdue sales  
 3 representative recalled the following scene: “I remember sitting at a round table with others from  
 4 my district in a regional meeting while everyone would stand up and state the highest dose that  
 5 they had suckered a doctor to prescribe. The entire region!!”

6           223. Sales representatives knew that the prescription opioids they were promoting were  
 7 dangerous. For example, May had only been at Purdue for two months when he found out that a  
 8 doctor he was calling on had just lost a family member to an OxyContin overdose.<sup>107</sup> And as  
 9 another sales representative wrote on a public forum:

10           Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when  
 11 they probably could have done okay on the 20mg (but their doctor got “sold” on  
 12 the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and  
 13 takes out a few 80's... next they're at a pill party with other teens and some kid  
 14 picks out a green pill from the bowl... they go to sleep and don't wake up (because  
 they don't understand respiratory depression) Stupid decision for a teen to  
 make...yes... but do they really deserve to die?

15           224. The Marketing Defendants rewarded their sales representatives with bonuses  
 16 when doctors whom they had detailed wrote prescriptions for their company's drug. Because of  
 17 this incentive system, sales representatives stood to gain significant bonuses if they had a pill  
 18 mill in their sales region. Indeed, Defendants often helped their sales representatives find and  
 19 target such pill mills.

20           225. The high volume of prescriptions written by doctors at pill mills translated  
 21 directly to higher bonuses for the sales representatives detailing those pill mills. As a result, sales  
 22 representatives continued to promote opioids even at known pill mills.

23           226. The Marketing Defendants applied this combination of intense competitive  
 24 pressure and lucrative financial incentives because they knew that sales representatives, with  
 25 their frequent in-person visits with prescribers, were incredibly effective. In fact, manufacturers'

26  
 27 <sup>107</sup> Remnick, *supra* note 98.

1 internal documents reveal that they considered sales representatives their “most valuable  
2 resource.”

3           **2. The Marketing Defendants bankrolled seemingly independent “front**  
4           **groups” to promote opioid use and fight restrictions on opioids.**

5           227. The Marketing Defendants funded, controlled, and operated third-party  
6 organizations that communicated to doctors, patients, and the public the benefits of opioids to  
7 treat chronic pain. These organizations—also known as “front groups”—appeared independent  
8 and unbiased. But in fact, they were but additional paid mouthpieces for the drug manufacturers.  
9 These front groups published prescribing guidelines and other materials that promoted opioid  
10 treatment as a way to address patients’ chronic pain. The front groups targeted doctors, patients,  
11 and lawmakers, all in coordinated efforts to promote opioid prescriptions.

12           228. The Marketing Defendants spent significant financial resources contributing to  
13 and working with these various front groups to increase the number of opioid prescriptions  
14 written.

15           229. The most prominent front group utilized by the Marketing Defendants was the  
16 **American Pain Foundation (APF)**, which received more than \$10 million from opioid drug  
17 manufacturers, including Defendants, from 2007 through 2012. For example, Purdue contributed  
18 \$1.7 million and Endo also contributed substantial sums to the APF.<sup>108</sup>

19           230. Throughout its existence, APF’s operating budget was almost entirely comprised  
20 of contributions from prescription opioid manufacturers. For instance, nearly 90% of APF’s \$5  
21 million annual budget in 2010 came from “donations” from some of the Marketing Defendants,  
22 and by 2011, APF was entirely dependent on grants from drug manufacturers, including from  
23 Purdue and Endo. Not only did Defendants control APF’s purse strings, APF’s board of directors  
24 was comprised of doctors who were on Defendants’ payrolls, either as consultants or speakers at  
25 medical events.<sup>109</sup>

26 <sup>108</sup>Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15am),  
27 <https://www.propublica.org/article/the-champion-of-painkillers>.

<sup>109</sup> *Id.*

231. Although holding itself out as an independent advocacy group promoting patient well-being, APF consistently lobbied against federal and state proposals to limit opioid use.

232. Another prominent front group was the **American Academy of Pain Medicine** (AAPM), which has received over \$2.2 million in funding since 2009 from opioid drug manufacturers, including Defendants. Like APF, AAPM presented itself as an independent and non-biased advocacy group representing physicians practicing in the field of pain medicine, but in fact was just another mouthpiece the Marketing Defendants used to push opioids on doctors and patients.<sup>110</sup>

233. Both the APF and the AAPM published treatment guidelines and sponsored and hosted medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks. The treatment guidelines the front groups published—many of which are discussed in detail below—were particularly important to Defendants in ensuring widespread acceptance for opioid therapy to treat chronic pain. Defendants realized, just as the CDC has, that such treatment guidelines can “change prescribing practices,” because they appear to be unbiased sources of evidence-based information, even when they are in reality marketing materials.

234. For instance, the AAPM, in conjunction with the **American Pain Society** (APS), issued comprehensive guidelines in 2009 titled “Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Evidence Review” (“2009 Guidelines”). The 2009 Guidelines promoted opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence to support this statement. Unsurprisingly, the Marketing Defendants have widely referenced and promoted these guidelines, issued by front groups these Defendants funded and controlled. These 2009 Guidelines are still available online today.<sup>111</sup>

<sup>110</sup> Tracy Weber and Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14am), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

<sup>111</sup> *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, Am. Pain Soc’y, <http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cnccp.pdf> (last visited Aug. 30, 2019).



235. The **Alliance for Patient Access (APA)**, discussed above, was established in 2006, along with the firm that runs it, Woodberry Associates LLC. The APA describes itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care,” but its list of “Associate Members and Financial Supporters” contains thirty drug companies, including each of the Marketing Defendants named in this lawsuit. In addition, the APA’s board members include doctors who have received hundreds of thousands of dollars in payments from drug companies. As discussed above, the APA has been a vocal critic of policies restricting the flow of opioids and has supported efforts to curtail the DEA’s ability to stop suspicious orders of prescription drugs.

236. The “white paper” issued by the APA in 2013 also echoed a favorite narrative of the Marketing Defendants, the supposed distinction between “legitimate patients” on the one hand and “addicts” on the other, asserting that one “unintended consequence” of regulating pain medication would be that “[p]atients with legitimate medical needs feel stigmatized, treated like addicts.”<sup>112</sup>

237. Another group utilized by the Marketing Defendants to encourage opioid prescribing practices, a University of Wisconsin-based organization known as the **Pain & Policy Studies Group**, received \$2.5 million from pharmaceutical companies to promote opioid use and discourage the passing of regulations against opioid use in medical practice. The Pain & Policy Studies Group wields considerable influence over the nation’s medical schools as well as within the medical field in general.<sup>113</sup> Purdue was the largest contributor to the Pain & Policy Studies Group, paying approximately \$1.6 million between 1999 and 2010.<sup>114</sup>

238. The **Federation of State Medical Boards (FSMB)** of the United States is a national non-profit organization that represents the seventy-state medical and osteopathic boards

<sup>112</sup> *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, *supra* note 75.

<sup>113</sup> *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com, <https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/> (last visited Aug. 30, 2019).

<sup>114</sup> John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011), <http://archive.jsonline.com/watchdog/watchdogreports/120331689.html>.



1 of the United States and its territories and co-sponsors the United States Medical Licensing  
 2 Examination. Beginning in 1997, FSMB developed model policy guidelines around the treatment  
 3 of pain, including opioid use. The original initiative was funded by the Robert Wood Johnson  
 4 Foundation, but subsequently AAPM, APS, the University of Wisconsin Pain & Policy Studies  
 5 Group, and the American Society of Law, Medicine, & Ethics all made financial contributions to  
 6 the project.

7 239. FSMB's 2004 Model Policy encourages state medical boards "to evaluate their  
 8 state pain policies, rules, and regulations to identify *any regulatory restrictions or barriers that*  
 9 *may impede the effective use of opioids* to relieve pain."<sup>115</sup> (Emphasis added).

10 240. One of the most significant barriers to convincing doctors that opioids were safe  
 11 to prescribe to their patients for long-term treatment of chronic pain was the fact that many of  
 12 those patients would, in fact, become addicted to opioids. If patients began showing up at their  
 13 doctors' offices with obvious signs of addiction, the doctors would, of course, become concerned  
 14 and likely stop prescribing opioids. And, doctors might stop believing the Marketing Defendants'  
 15 claims that addiction risk was low.

16 241. To overcome this hurdle, the Marketing Defendants promoted a concept called  
 17 "pseudoaddiction." These Defendants told doctors that when their patients appeared to be  
 18 addicted to opioids—for example, asking for more and higher doses of opioids, increasing doses  
 19 themselves, or claiming to have lost prescriptions in order to get more opioids—this was not  
 20 actual addiction. Rather, the Marketing Defendants told doctors what appeared to be classic signs  
 21 of addiction were actually just signs of undertreated pain. The solution to this "pseudoaddiction":  
 22 more opioids. Instead of warning doctors of the risk of addiction and helping patients to wean  
 23 themselves off powerful opioids and deal with their actual addiction, the Marketing Defendants  
 24 pushed even more dangerous drugs onto patients.

25  
 26  
 27 <sup>115</sup> *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Fed'n of St. Med. Boards of the  
 U.S., Inc. (May 2004), [https://dprfiles.delaware.gov/medicalpractice/Model\\_Policy\\_Treatment\\_Pain.pdf](https://dprfiles.delaware.gov/medicalpractice/Model_Policy_Treatment_Pain.pdf).

242. The FSMB's Model Policy gave a scientific veneer to this fictional and overstated concept. The policy defines "pseudoaddiction" as "[t]he iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction" and states that these behaviors "resolve upon institution of effective analgesic therapy."<sup>116</sup>

243. In May 2012, Senate Finance Committee Chairman Max Baucus and senior Committee member Chuck Grassley initiated an investigation into the connections of the Marketing Defendants with medical groups and physicians who have advocated increased opioid use.<sup>117</sup> In addition to Purdue, Endo, and Janssen, the senators sent letters to APF, APS, AAPM, FSMB, the University of Wisconsin Pain & Policy Studies Group, the Joint Commission on Accreditation of Healthcare Organization, and the Center for Practical Bioethics, requesting from each "a detailed account of all payments/transfers received from corporations and any related corporate entities and individuals that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present."<sup>118</sup>

244. On the same day as the senators' investigation began, APF announced that it would "cease to exist, effective immediately."<sup>119</sup>

### 3. "It was pseudoscience": the Marketing Defendants paid prominent physicians to promote their products.

245. The Marketing Defendants retained highly credentialed medical professionals to promote the purported benefits and minimal risks of opioids. Known as "Key Opinion Leaders" or "KOLs," these medical professionals were often integrally involved with the front groups

<sup>116</sup> *Id.*

<sup>117</sup> Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups, U.S. Senate Comm. on Fin. (May 8, 2012), <https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups>.

<sup>118</sup> Letter from U.S. Senate Comm. on Fin. to Am. Pain Found. (May 8, 2012), <https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Foundation2.pdf>.

<sup>119</sup> Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57pm), <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups>.

described above. The Marketing Defendants paid these KOLs substantial amounts to present at Continuing Medical Education (“CME”) seminars and conferences, and to serve on their advisory boards and on the boards of the various front groups.

246. The Marketing Defendants also identified doctors to serve as speakers or attend all-expense-paid trips to programs with speakers.<sup>120</sup> The Marketing Defendants used these trips and programs—many of them lavish affairs—to incentivize the use of opioids while downplaying their risks, bombarding doctors with messages about the safety and efficacy of opioids for treating long-term pain. Although often couched in scientific certainty, the Marketing Defendants’ messages were false and misleading, and helped to ensure that millions of Americans would be exposed to the profound risks of these drugs.

247. It is well documented that this type of pharmaceutical company symposium influences physicians’ prescribing, even though physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.<sup>121</sup> For example, doctors who were invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.<sup>122</sup>

248. The KOLs gave the impression they were independent sources of unbiased information, while touting the benefits of opioids through their presentations, articles, and books. KOLs also served on committees and helped develop guidelines such as the 2009 Guidelines described above that strongly encouraged the use of opioids to treat chronic pain.

249. One of the most prominent KOLs for the Marketing Defendants’ opioids was Dr. Russell Portenoy. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling

<sup>120</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 103.

<sup>121</sup> *Id.*

<sup>122</sup> Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — “We’re only just getting started”*, Los Angeles Times (Dec. 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

1 message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been  
2 studied.’”<sup>123</sup>

3 250. As one organizer of CME seminars, who worked with Portenoy and Purdue,  
4 pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some  
5 papers, made some speeches, and his influence would have been minor. With Purdue’s millions  
6 behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”<sup>124</sup>

7 251. In recent years, some of the Marketing Defendants’ KOLs have conceded that  
8 many of their past claims in support of opioid use lacked evidence or support in the scientific  
9 literature.<sup>125</sup> Dr. Portenoy himself specifically admitted that he overstated the drugs’ benefits and  
10 glossed over their risks, and that he “gave innumerable lectures in the late 1980s and ‘90s about  
11 addiction that weren’t true.”<sup>126</sup> He mused, “Did I teach about pain management, specifically  
12 about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012,  
13 I guess I did . . . We didn’t know then what we know now.”<sup>127</sup>

14 252. Dr. Portenoy did not need “the standards of 2012” to discern evidence-based  
15 science from baseless claims, however. When interviewed by journalist Barry Meier for his 2003  
16 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to  
17 have always to live with that one.”<sup>128</sup>

18 253. Dr. Portenoy was perhaps the most prominent KOL for prescription opioids, but  
19 he was far from the only one. In fact, Dr. Portenoy and a doctor named Perry Fine co-wrote A  
20 *Clinical Guide to Opioid Analgesia*, which contained statements that conflict with the CDC’s  
21  
22

23 <sup>123</sup> Quinones, *supra* note 76, at 314.

24 <sup>124</sup> *Id.* at 136.

25 <sup>125</sup> See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012),  
<http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (finding that a key Endo KOL acknowledged that opioid marketing went too far).

26 <sup>126</sup> Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17,  
2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

27 <sup>127</sup> *Id.*

<sup>128</sup> Meier, *supra* note 15, at 277.

2016 *Guideline for Prescribing Opioids for Chronic Pain*, such as the following examples regarding respiratory depression and addiction:

At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.<sup>129</sup>

254. Dr. Fine is a Professor of Anesthesiology at the University of Utah School of Medicine's Pain Research Center. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.<sup>130</sup>

255. In 2011, he and Dr. Scott Fishman, discussed below, published a letter in *JAMA* called "Reducing Opioid Abuse and Diversion," which emphasized the importance of maintaining patient access to opioids.<sup>131</sup> The editors of *JAMA* found that both doctors had provided incomplete financial disclosures and made them submit corrections listing all their ties to the prescription painkiller industry.<sup>132</sup>

256. Dr. Fine also failed to provide full disclosures as required by his employer, the University of Utah. For example, Dr. Fine told the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's

<sup>129</sup> Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

<sup>130</sup> Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Oct. 5, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

<sup>131</sup> Perry G. Fine, MD and Scott M. Fishman, MD, *Reducing Opioid Abuse and Diversion*, 306 (4) JAMA 381 (July 27, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104144?redirect=true>.

<sup>132</sup> *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1446 (Oct. 5, 2011), <https://jamanetwork.com/journals/jama/fullarticle/1104453>.

1 website states that the company paid him \$32,017 for consulting, promotional talks, meals and  
2 travel that year.<sup>133</sup>

3 257. In 2012, along with other KOLs, Dr. Fine was investigated for his ties to drug  
4 companies as part of the Senate investigation of front groups described above. When Marianne  
5 Skolek, a reporter for the online news outlet Salem-News.com and a critic of opioid overuse,  
6 wrote an article about him and another KOL being investigated, Dr. Fine fired back, sending a  
7 letter to her editor accusing her of poor journalism and saying that she had lost whatever  
8 credibility she may have had. He criticized her for linking him to Purdue, writing, “I have never  
9 had anything to do with Oxycontin development, sales, marketing or promotion; I have never  
10 been a Purdue Pharma speaker”—neglecting to mention, of course, that he served on Purdue’s  
11 advisory board, as the *JAMA* editors had previously forced him to disclose.<sup>134</sup>

12 258. Another Utah physician, Dr. Lynn Webster, was the director of Lifetree Clinical  
13 Research & Pain Clinic in Salt Lake City from 1990 to 2010, and in 2013 was the president of  
14 AAPM (one of the front groups discussed above). Dr. Webster developed a five-question survey  
15 he called the Opioid Risk Tool, which he asserted would “predict accurately which individuals  
16 may develop aberrant behaviors when prescribed opioids for chronic pain.”<sup>135</sup> He published  
17 books titled *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of*  
18 *Us* and *Avoiding Opioid Abuse While Managing Pain*.

19 259. Dr. Webster and the Lifetree Clinic were investigated by the DEA for  
20 overprescribing opioids after twenty patients died from overdoses. In keeping with the opioid  
21 industry’s promotional messages, Dr. Webster apparently believed the solution to patients’  
22 tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.  
23 Tina Webb, a Lifetree patient who overdosed in 2007, was taking as many as thirty-two pain  
24

25 <sup>133</sup> Weber and Ornstein, *Two Leaders in Pain Treatment*, *supra* note 110.

26 <sup>134</sup> Marianne Skolek, *Doctor Under Senate Investigation Lashes Out at Journalist*, Salem News (Aug. 12, 2012,  
8:45pm), <http://www.salem-news.com/articles/august122012/perry-fine-folo-ms.php>.

27 <sup>135</sup> Lynn Webster and RM Webster, *Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool* 6 (6) Pain Med. 432 (Nov.-Dec. 2005), <https://www.ncbi.nlm.nih.gov/pubmed/16336480>.

1 pills a day in the year before she died, all while under doctor supervision.<sup>136</sup> Carol Ann Bosley,  
 2 who sought treatment for pain at Lifetree after a serious car accident and multiple spine  
 3 surgeries, quickly became addicted to opioids and was prescribed increasing quantities of pills; at  
 4 the time of her death, she was on seven different medications totaling approximately 600 pills a  
 5 month.<sup>137</sup> Another woman, who sought treatment from Lifetree for chronic low back pain and  
 6 headaches, died at age forty-two after Lifetree clinicians increased her prescriptions to fourteen  
 7 different drugs, including multiple opioids, for a total of 1,158 pills a month.<sup>138</sup>

8 260. By these numbers, Lifetree resembles the pill mills and “bad actors” that the  
 9 Marketing Defendants blame for opioid overuse. But Dr. Webster was an integral part of  
 10 Defendants’ marketing campaigns, a respected pain specialist who authored numerous CMEs  
 11 sponsored by Endo and Purdue. And the Marketing Defendants promoted his Opioid Risk Tool  
 12 and similar screening questionnaires as measures that allow powerful opioids to be prescribed for  
 13 chronic pain.

14 261. Even in the face of patients’ deaths, Dr. Webster continues to promote a pro-  
 15 opioid agenda, even asserting that alternatives to opioids are risky because “[i]t’s not hard to  
 16 overdose on NSAIDs or acetaminophen.”<sup>139</sup> He argued on his website in 2015 that DEA  
 17 restrictions on the accessibility of hydrocodone harm patients, and in 2017 tweeted in response to  
 18 CVS Caremark’s announcement that it will limit opioid prescriptions that “CVS Caremark’s new  
 19 opioid policy is wrong, and it won’t stop illegal drugs.”<sup>140</sup>

20 262. Another prominent KOL is Dr. Scott M. Fishman, the Chief of the Department of  
 21 Pain Medicine at University of California, Davis. He has served as president of APF and AAPM,  
 22

23 <sup>136</sup> Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national*  
 24 *opioid epidemic*, Deseret News (Oct. 26, 2017, 12:01am), [https://www.deseretnews.com/article/900002328/the-](https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html)  
[untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html](https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html).

25 <sup>137</sup> Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN (Dec. 20, 2013,  
 7:06am), <http://www.cnn.com/2013/12/20/health/pain-pillar/index.html>.

26 <sup>138</sup> *Id.*

27 <sup>139</sup> *APF releases opioid medication safety module*, Drug Topics (May 10, 2011),  
<https://www.drugtopics.com/clinical-news/apf-releases-opioid-medication-safety-module>.

<sup>140</sup> Lynn Webster, MD (@LynnRWebsterMD), Twitter (Dec. 7, 2017, 1:45pm),  
<https://twitter.com/LynnRWebsterMD/status/938887130545360898>.



1 and as a consultant and a speaker for Purdue, in addition to providing the company grant and  
 2 research support. He also has had financial relationships with Endo and Janssen. He wrote a  
 3 book for the FSMB called *Responsible Opioid Use: A Physician's Guide*, which was distributed  
 4 to over 165,000 physicians in the U.S.

5 263. Dr. Fishman and Dr. Fine, along with Dr. Seddon Savage, published an editorial  
 6 in *The Seattle Times* in 2010, arguing that Washington legislation proposed to combat  
 7 prescription opioid abuse would harm patients, particularly by requiring chronic pain patients to  
 8 consult with a pain specialist before receiving a prescription for a moderate to high dose of an  
 9 opioid.<sup>141</sup>

10 264. These KOLs and others—respected specialists in pain medicine—proved to be  
 11 highly effective spokespeople for the Marketing Defendants.

12 **4. The Marketing Defendants used “unbranded” advertising as a platform for**  
 13 **their misrepresentations about opioids.**

14 265. The Marketing Defendants also aggressively promoted opioids through  
 15 “unbranded advertising” to generally tout the benefits of opioids without specifically naming a  
 16 particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease  
 17 awareness”—encouraging consumers to “talk to your doctor” about a certain health condition  
 18 without promoting a specific product. A trick often used by pharmaceutical companies,  
 19 unbranded advertising gives the pharmaceutical companies considerable leeway to make  
 20 sweeping claims about health conditions or classes of drugs. In contrast, a “branded”  
 21 advertisement that identifies a specific medication and its indication (i.e., the condition which the  
 22 drug is approved to treat) must also include possible side effects and contraindications—what the  
 23 FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is  
 24 also subject to FDA review for consistency with the drug’s FDA-approved label.

25  
 26 <sup>141</sup> Perry G. Fine, Scott M. Fishman, and Seddon R. Savage, *Bill to combat prescription abuse really will harm*  
 27 *patients in pain*, *Seattle Times* (Mar. 16, 2010, 4:39pm),  
[http://old.seattletimes.com/html/opinion/2011361572\\_guest17fine.html](http://old.seattletimes.com/html/opinion/2011361572_guest17fine.html).



266. Unbranded advertising allows pharmaceutical manufacturers to sidestep those requirements; “fair balance” and consistency with a drug’s label are not required.

267. By engaging in unbranded advertising, the Marketing Defendants were and are able to avoid FDA review and issue general statements to the public including that opioids improve function, that addiction usually does not occur, and that withdrawal can easily be managed. The Marketing Defendants’ unbranded advertisements either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

268. Through the various marketing channels described above—all of which the Marketing Defendants controlled, funded, and facilitated, and for which they are legally responsible—these Defendants made false or misleading statements about opioids despite the lack of scientific evidence to support their claims, while omitting the true risk of addiction and death.

**E. Specific Misrepresentations Made by the Marketing Defendants.**

269. All the Marketing Defendants have made and/or continue to make false or misleading claims in the following areas: (1) the low risk of addiction to opioids, (2) opioids’ efficacy for chronic pain and ability to improve patients’ quality of life with long-term use, (3) the lack of risk associated with higher dosages of opioids, (4) the need to prescribe more opioids to treat withdrawal symptoms, and (5) that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids for chronic use. These illustrative but non-exhaustive categories of the Marketing Defendants’ misrepresentations about opioids are described in detail below.

**1. The Marketing Defendants falsely claimed that the risk of opioid abuse and addiction was low.**

270. Collectively, the Marketing Defendants have made a series of false and misleading statements about the low risk of addiction to opioids over the past twenty years. The Marketing Defendants have also failed to take sufficient remedial measures to correct their false and misleading statements.

1           271. The Marketing Defendants knew that many physicians were hesitant to prescribe  
 2           opioids other than for acute or cancer-related pain because of concerns about addiction. Because  
 3           of this general perception, sales messaging about the low risk of addiction was a fundamental  
 4           prerequisite misrepresentation.

5           272. Purdue launched OxyContin in 1996 with the statement that OxyContin's  
 6           patented continuous-release mechanism "is believed to reduce the abuse liability." This  
 7           statement, which appeared in OxyContin's label and which sales representatives were taught to  
 8           repeat verbatim, was unsupported by any studies, and was patently false. The continuous-release  
 9           mechanism was simple to override, and the drug correspondingly easy to abuse. This fact was  
 10          known, or should have been known, to Purdue prior to its launch of OxyContin, because people  
 11          had been circumventing the same continuous-release mechanism for years with MS Contin,  
 12          which in fact commanded a high street price because of the dose of pure narcotic it delivered. In  
 13          addition, with respect to OxyContin, Purdue researchers notified company executives, including  
 14          Raymond and Richard Sackler, by email that patients in their clinical trials were abusing the drug  
 15          despite the timed-release mechanism.<sup>142</sup>

16          273. In 2007, as noted above, Purdue pleaded guilty to misbranding a drug, a felony  
 17          under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a)(2). As part of its guilty plea,  
 18          Purdue agreed that certain Purdue supervisors and employees had, "with the intent to defraud or  
 19          mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and  
 20          diversion, and less likely to cause tolerance and withdrawal than other pain medications" in the  
 21          following ways:

22               Trained PURDUE sales representatives and told some health care providers that it  
 23               was more difficult to extract the oxycodone from an OxyContin tablet for the  
 24               purpose of intravenous abuse, although PURDUE's own study showed that a drug  
 25               abuser could extract approximately 68% of the oxycodone from a single 10mg  
 26               OxyContin tablet by crushing the tablet, stirring it in water, and drawing the  
 27               solution through cotton into a syringe;

<sup>142</sup> WBUR On Point interview, *supra* note 21.

1 Told PURDUE sales representatives they could tell health care providers that  
2 OxyContin potentially creates less chance for addiction than immediate-release  
opioids;

3 Sponsored training that taught PURDUE sales supervisors that OxyContin had  
4 fewer “peak and trough” blood level effects than immediate-release opioids  
resulting in less euphoria and less potential for abuse than short-acting opioids;

5 Told certain health care providers that patients could stop therapy abruptly without  
6 experiencing withdrawal symptoms and that patients who took OxyContin would  
not develop tolerance to the drug; and

7 Told certain health care providers that OxyContin did not cause a “buzz” or  
8 euphoria, caused less euphoria, had less addiction potential, had less abuse  
9 potential, was less likely to be diverted than immediate-release opioids, and could  
be used to “weed out” addicts and drug seekers.<sup>143</sup>

10 274. All these statements were false and misleading. But Purdue had not stopped there.  
11 Purdue—and later the Defendants—manipulated scientific research and utilized respected  
12 physicians as paid spokespeople to convey its misrepresentations about low addiction risk in  
13 much more subtle and pervasive ways, so that the idea that opioids used for chronic pain posed a  
14 low addiction risk became so widely accepted in the medical community that Defendants were  
15 able to continue selling prescription opioids for chronic pain—even after Purdue’s criminal  
16 prosecution.

17 275. When it launched OxyContin, Purdue knew it would need data to overcome  
18 decades of wariness regarding opioid use. It needed some sort of research to back up its  
19 messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as  
20 part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants)  
21 found this “research” in the form of a one-paragraph letter to the editor published in the *New*  
22 *England Journal of Medicine* (NEJM) in 1980.

23 276. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of  
24 addiction “rare” for patients treated with opioids.<sup>144</sup> They had analyzed a database of hospitalized  
25

26 <sup>143</sup> *United States v. Purdue Frederick Co.*, *supra* note 25; *see also*, Plea Agreement, *United States v. Purdue*  
*Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

27 <sup>144</sup> Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.*  
123 (Jan. 10, 1980), <https://www.nejm.org/doi/10.1056/NEJM198001103020221>.

1 patients who were given opioids in a controlled setting to ease suffering from acute pain. These  
 2 patients were not given long-term opioid prescriptions or provided opioids to administer to  
 3 themselves at home, nor was it known how frequently or infrequently and in what doses the  
 4 patients were given their narcotics. Rather, it appears the patients were treated with opioids for  
 5 short periods of time under in-hospital doctor supervision.

6 **ADDICTION RARE IN PATIENTS TREATED  
 7 WITH NARCOTICS**

8 *To the Editor:* Recently, we examined our current files to deter-  
 9 mine the incidence of narcotic addiction in 39,946 hospitalized  
 10 medical patients<sup>1</sup> who were monitored consecutively. Although  
 11 there were 11,882 patients who received at least one narcotic prepa-  
 12 ration, there were only four cases of reasonably well documented  
 13 addiction in patients who had no history of addiction. The addic-  
 14 tion was considered major in only one instance. The drugs im-  
 15 plicated were meperidine in two patients,<sup>2</sup> Percodan in one, and  
 16 hydromorphone in one. We conclude that despite widespread use of  
 17 narcotic drugs in hospitals, the development of addiction is rare in  
 18 medical patients with no history of addiction.

19 JANE PORTER  
 20 HERSHEL JICK, M.D.  
 21 Boston Collaborative Drug  
 22 Surveillance Program  
 23 Waltham, MA 02154 Boston University Medical Center

- 24 1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.  
 25 Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.  
 26 2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical  
 27 patients. J Clin Pharmacol. 1978; 18:180-8.

277. As Dr. Jick explained to a journalist years later, he submitted the statistics to  
 278 NEJM as a letter because the data were not robust enough to be published as a study, and that  
 279 one could not conclude anything about long-term use of opioids from his figures.<sup>145</sup> Dr. Jick also  
 280 recalled that no one from drug companies or patient advocacy groups contacted him for more  
 281 information about the data.<sup>146</sup>

282 278. Nonetheless, the Marketing Defendants regularly invoked this letter as proof of  
 283 the low addiction risk in connection with taking opioids despite its obvious shortcomings. These

<sup>145</sup> Meier, *supra* note 15, at 174.

<sup>146</sup> *Id.*

1 Defendants' egregious misrepresentations based on this letter included claims that *less than one*  
 2 *percent* of opioid users become addicted.

3 279. The limited facts of the study did not deter the Marketing Defendants from using  
 4 it as definitive proof of opioids' safety. The enormous impact of the Marketing Defendants'  
 5 misleading amplification of this letter was well documented in another letter published in NEJM  
 6 on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited  
 7 and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

8 [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily  
 9 and uncritically cited as evidence that addiction was rare with long-term opioid  
 10 therapy. We believe that this citation pattern contributed to the North American  
 11 opioid crisis by helping to shape a narrative that allayed prescribers' concerns about  
 the risk of addiction associated with long-term opioid therapy . . .<sup>147</sup>

12 280. Unfortunately, by the time of this analysis and the CDC's findings in 2016, the  
 13 damage had already been done. "It's difficult to overstate the role of this letter," said Dr. David  
 14 Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that  
 15 helped the opiate manufacturers convince front-line doctors that addiction is not a concern."<sup>148</sup>

16 281. The Marketing Defendants successfully manipulated the 1980 Porter and Jick  
 17 letter as the "evidence" supporting their fundamental misrepresentation that the risk of opioid  
 18 addiction was low when opioids were prescribed to treat pain. For example, in its 1996 press  
 19 release announcing the release of OxyContin, Purdue advertised that the "fear of addiction is  
 20 exaggerated" and quoted the chairman of the American Pain Society Quality of Care Committee,  
 21  
 22  
 23  
 24

25 <sup>147</sup> Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al  
 26 Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Eng. J.  
 Med. 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

27 <sup>148</sup> *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT News (May 31, 2017),  
<https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

1 who claimed that “there is very little risk of addiction from the proper uses of these [opioid]  
2 drugs for pain relief.”<sup>149</sup>

3 PR Newswire

4  
5 **May** 31, 1996, Friday - 15:47 Eastern Time

6 **NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM**  
7 **PERSISTENT**

8 **The fear of addiction is exaggerated.**

9 One cause of patient resistance to appropriate pain treatment – the  
10 fear of addiction – is largely unfounded. According to Dr. Max,  
11 “Experts agree that most pain caused by surgery or cancer can be  
12 relieved, primarily by carefully adjusting the dose of opioid  
13 (narcotic) pain reliever to each patient’s need, and that there is very  
14 little risk of addiction from the proper uses of these drugs for pain  
15 relief.”

16 Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in  
17 Norwalk, Connecticut, agrees with this assessment. “Proper use of  
18 medication is an essential weapon in the battle against persistent  
19 pain. But too often fear, misinformation and poor communication stand  
20 in the way of their legitimate use.”

21  
22 282. Dr. Portenoy, the Purdue KOL mentioned previously, also stated in a promotional  
23 video from the 1990s that “the likelihood that the treatment of pain using an opioid drug which is  
24 prescribed by a doctor will lead to addiction is extremely low.”<sup>150</sup>



28 <sup>149</sup> Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain* (May 31, 1996,  
29 3:47pm), <http://documents.latimes.com/oxycontin-press-release-1996/>.

30 <sup>150</sup> Catan and Perez, *supra* note 126.



283. Purdue also specifically used the Porter and Jick letter in its 1998 promotional video, “I got my life back,” in which Dr. Alan Spanos says, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.”<sup>151</sup>



284. The Porter and Jick letter was also used on Purdue’s “Partners Against Pain” website, which was available in the early 2000s, where Purdue claimed that the addiction risk with OxyContin was very low.<sup>152</sup>

285. The Porter and Jick letter was used frequently in literature given to prescribing physicians and to patients who were prescribed OxyContin.<sup>153</sup>

286. In addition to the Porter and Jick letter, the Marketing Defendants exaggerated the significance of a study published in 1986 regarding cancer patients treated with opioids. Conducted by Dr. Portenoy and another pain specialist, Dr. Kathleen Foley, the study involved only 38 patients, who were treated for non-malignant cancer pain with low doses of opioids (the majority were given less than 20 MME/day, the equivalent of only 13 mg of oxycodone).<sup>154</sup> Of these thirty-eight patients, only two developed problems with opioid abuse, and Dr. Portenoy and

<sup>151</sup> Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyel> (last visited Aug. 30, 2019) (emphasis added).

<sup>152</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 103.

<sup>153</sup> Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma’s Marketing* (Aug. 22, 2001), <https://web.archive.org/web/20170212210143/https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf>.

<sup>154</sup> Russell K. Portenoy and Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 *Pain* 171-86 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.



1 Dr. Foley concluded that “opioid maintenance therapy can be a safe, salutary and more humane  
 2 alternative to the options of surgery or no treatment in those patients with intractable non-  
 3 malignant pain and no history of drug abuse . . .”<sup>155</sup> Notwithstanding the small sample size, low  
 4 doses of opioids involved, and the fact that all the patients were cancer patients, the Marketing  
 5 Defendants used this study as “evidence” that high doses of opioids were safe for the treatment  
 6 of chronic non-cancer pain.

7 287. The Marketing Defendants’ repeated misrepresentations about the low risk of  
 8 opioid addiction were so effective that this concept became part of the conventional wisdom. Dr.  
 9 Nathaniel Katz, a pain specialist, recalls learning in medical school that previous fears about  
 10 addiction were misguided, and that doctors should feel free to allow their patients the pain relief  
 11 that opioids can provide. He did not question this until one of his patients died from an overdose.  
 12 Then, he searched the medical literature for evidence of the safety and efficacy of opioid  
 13 treatment for chronic pain. “There’s not a shred of research on the issue. All these so-called  
 14 experts in pain are dedicated and have been training me that opioids aren’t as addictive as we  
 15 thought. But what is that based on? It was based on nothing.”<sup>156</sup>

16 288. At a hearing before the House of Representatives’ Subcommittee on Oversight  
 17 and Investigations of the Committee on Energy and Commerce in August 2001, Purdue  
 18 continued to emphasize “legitimate” treatment, dismissing cases of overdose and death as  
 19 something that would not befall “legitimate” patients: “Virtually all of these reports involve  
 20 people who are abusing the medication, not patients with legitimate medical needs under the  
 21 treatment of a healthcare professional.”<sup>157</sup>

22 289. Purdue spun this baseless “legitimate use” distinction out even further in a patient  
 23 brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a  
 24

25 <sup>155</sup> *Id.*

26 <sup>156</sup> Quinones, *supra* note 76, at 188-89.

27 <sup>157</sup> *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/pdf/CHRG-107hhrg75754.pdf>.

1 Partner Against Pain.” In response to the question, “Aren’t opioid pain medications like  
 2 OxyContin Tablets ‘addicting’? Even my family is concerned about this,” Purdue claimed that  
 3 there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

4 Drug addiction means using a drug to get “high” rather than to relieve pain. You  
 5 are taking opioid pain medication for medical purposes. The medical purposes are  
 6 clear and the effects are beneficial, not harmful.

7 290. Similarly, Dr. David Haddox, Senior Medical Director for Purdue, cavalierly  
 8 stated, “[w]hen this medicine is used appropriately to treat pain under a doctor’s care, it is not  
 9 only effective, it is safe.”<sup>158</sup> He went so far as to compare OxyContin to celery, because even  
 10 celery would be harmful if injected: “If I gave you a stalk of celery and you ate that, it would be  
 11 healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be  
 12 good.”<sup>159</sup>

13 291. Purdue sales representatives also repeated these misstatements regarding the low  
 14 risk for addiction to doctors across the country.<sup>160</sup> Its sales representatives targeted primary care  
 15 physicians in particular, downplaying the risk of addiction and, as one doctor observed,  
 16 “promot[ing] among primary care physicians a more liberal use of opioids.”<sup>161</sup>

17 292. Purdue sales representatives were instructed to “distinguish between iatrogenic  
 18 addiction (<1% of patients) and substance abusers/diversion (about 10% of the population abuse  
 19 something: weed; cocaine; heroin; alcohol; valium; etc.).”<sup>162</sup>

20 293. Purdue also marketed OxyContin for a wide variety of conditions and to doctors  
 21 who were not adequately trained in pain management.<sup>163</sup>

24 <sup>158</sup> Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, Charleston Gazette, Feb. 9, 2001.

25 <sup>159</sup> *Id.*

26 <sup>160</sup> Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007),  
<http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

27 <sup>161</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 103.

<sup>162</sup> Meier, *supra* note 15, at 269.

<sup>163</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 37.

294. As of 2003, Purdue's Patient Information guide for OxyContin contained the following language regarding addiction:

Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients.

295. Although Purdue has acknowledged it has made some misrepresentations about the safety of its opioids,<sup>164</sup> it has done nothing to address the ongoing harms of their misrepresentations; in fact, it continues to make those misrepresentations today.

296. Defendant Endo also made dubious claims about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that "[p]eople who take opioids as prescribed usually do not become addicted."<sup>165</sup> The website has since been taken down.

297. In another website, PainAction.com—which is still currently available today—Endo also claimed that "most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."<sup>166</sup>

298. In a pamphlet titled "Understanding Your Pain: Taking Oral Opioid Analgesics," Endo assured patients that addiction is something that happens to people who take opioids for reasons other than pain relief, "such as unbearable emotional problems"<sup>167</sup>:

<sup>164</sup> Following the conviction in 2007 of three of its executives for misbranding OxyContin, Purdue released a statement in which they acknowledged their false statements. "Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information."

<sup>165</sup> German Lopez, *The growing number of lawsuits against opioid companies, explained*, Vox (Feb. 27, 2018), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>.

<sup>166</sup> *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), <https://www.painaction.com/opioid-medication-addiction/>.

<sup>167</sup> *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharms. (2004), [http://www.thblack.com/links/RSD/Understand\\_Pain\\_Opioid\\_Analgesics.pdf](http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf).

Some questions you may have are:

*Is it wrong to take opioids for pain?*

- ◆ No. Pain relief is an important medical reason to take opioids as prescribed by your doctor. Addicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.

*How can I be sure I'm not addicted?*

- ◆ Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- ◆ Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

299. In addition, Endo made statements in pamphlets and publications that most health care providers who treat people with pain agree that most people do not develop an addiction problem. These statements also appeared on websites sponsored by Endo, such as Opana.com.

300. In its currently active website, PrescribeResponsibly.com, Defendant Janssen states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”<sup>168</sup>

## Use of Opioid Analgesics in Pain Management



### *Other Opioid Analgesic Concerns*

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.<sup>15,16</sup> By the same token, patients report similar concerns about developing an addiction to opioid analgesics.<sup>17</sup> While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.<sup>18</sup>



301. Similarly, in a 2009 patient education video titled “Finding Relief: Pain Management for Older Adults,” Janssen sponsored a video by the American Academy of Pain

<sup>168</sup> Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <https://web.archive.org/web/20190221055503/http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

1 Medicine that indicated that opioids are rarely addictive. The video has since been taken  
2 down.<sup>169</sup>

3 302. Janssen also approved and distributed a patient education guide in 2009 that  
4 attempted to counter the “myth” that opioids are addictive, claiming that “[m]any studies show  
5 that opioids are rarely addictive when used properly for the management of chronic pain.”<sup>170</sup>

6 303. In addition, all the Marketing Defendants used third parties and front groups to  
7 further their false and misleading statements about the safety of opioids.

8 304. For example, in testimony for the Hearing to Examine the Effects of the Painkiller  
9 OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and  
10 Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the  
11 organization which, as described above, received the majority of its funding from opioid  
12 manufacturers, including Purdue, stated that “opioids are safe and effective, and only in rare  
13 cases lead to addiction.”<sup>171</sup> Along with Dr. Giglio’s testimony, the APF submitted a short  
14 background sheet on “the scope of the undertreatment of pain in the U.S.,” which asserted that  
15 “opioids are often the best” treatment for pain that hasn’t responded to other techniques, but that  
16 patients and many doctors “lack even basic knowledge about these options and fear that powerful  
17 pain drugs will [c]ause addiction.” According to the APF, “most studies show that less than 1%  
18 of patients become addicted, which is medically different from becoming physically  
19 dependent.”<sup>172</sup>

20 305. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio  
21 appeals court in December 2002, in which it claimed that “medical leaders have come to  
22  
23

24  
25 <sup>169</sup> Molly Huff, *Finding Relief: Pain Management for Older Adults*, Ctrs. for Pain Mgmt. (Mar. 9, 2011),  
<http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults>.

26 <sup>170</sup> Lopez, *supra* note 165.

27 <sup>171</sup> *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*,  
107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain  
Foundation), <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

<sup>172</sup> *Id.*



1 understand that the small risk of abuse does not justify the withholding of these highly effective  
2 analgesics from chronic pain patients.”<sup>173</sup>

3 306. In a 2007 publication titled “Treatment Options: A Guide for People Living with  
4 Pain,” APF downplayed the risk of addiction and argued that concern about this risk should not  
5 prevent people from taking opioids: “Restricting access to the most effective medications for  
6 treating pain is not the solution to drug abuse or addiction.”<sup>174</sup> APF also tried to normalize the  
7 dangers of opioids by listing opioids as one of several “[c]ommon drugs that can cause physical  
8 dependence,” including steroids, certain heart medications, and caffeine.<sup>175</sup>

9 307. The Marketing Defendants’ repeated statements about the low risk of addiction  
10 when taking opioids as prescribed for chronic pain were blatantly false and were made with  
11 reckless disregard for the potential consequences.

12 **2. The Marketing Defendants falsely claimed that opioids were proven effective**  
13 **for chronic pain and would improve quality of life.**

14 308. Not only did the Marketing Defendants falsely claim that the risk of addiction to  
15 prescription opioids was low, these Defendants represented that there was a significant upside to  
16 long-term opioid use, including that opioids could restore function and improve quality of life.<sup>176</sup>

17 309. Such claims were viewed as a critical part of the Marketing Defendants’  
18 marketing strategies. For example, an internal Purdue report from 2001 noted the lack of data  
19 supporting improvement in quality of life with OxyContin treatment:

20 Janssen has been stressing decreased side effects, especially constipation, as well  
21 as patient quality of life, as supported by patient rating compared to sustained  
22 release morphine... We do not have such data to support OxyContin promotion... In  
addition, Janssen has been using the “life uninterrupted” message in promotion of

23 <sup>173</sup> Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio  
24 Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P.*, Appeal No. CA 2002 09  
0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

25 <sup>174</sup> *Treatment Options: A Guide for People Living with Pain*, Am. Pain Found.,  
26 <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Aug. 30, 2019).

27 <sup>175</sup> *Id.*

<sup>176</sup> This case *does not* request or require the Court to specifically adjudicate whether opioids are appropriate for the  
treatment of chronic, non-cancer pain—though the scientific evidence strongly suggests they are not.



1 Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less  
2 about their pain.” This is a competitive advantage based on our inability to make  
any quality of life claims.<sup>177</sup>

3 310. Despite the lack of data supporting improvement in quality of life, Purdue ran a  
4 full-page ad for OxyContin in the Journal of the American Medical Association in 2002,  
5 proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside  
6 his grandson.<sup>178</sup> This ad earned a warning letter from the FDA, which admonished, “It is  
7 particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that  
8 patients can die from taking OxyContin.”<sup>179</sup>

9 311. Purdue also consistently tried to steer any concern away from addiction and focus  
10 on its false claims that opioids were effective and safe for treating chronic pain. At a hearing  
11 before the House of Representatives’ Subcommittee on Oversight and Investigations of the  
12 Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice  
13 President and Chief Operating Officer of Purdue, testified that “even the most vocal critics of  
14 opioid therapy concede the value of OxyContin in the legitimate treatment of pain,” and that  
15 “OxyContin has proven itself an effective weapon in the fight against pain, returning many  
16 patients to their families, to their work, and to their ability to enjoy life.”<sup>180</sup>

17 312. Purdue sponsored the development and distribution of an APF guide in 2011  
18 which claimed that “multiple clinical studies have shown that opioids are effective in improving  
19 daily function, psychological health, and health-related quality of life for chronic pain patients.”  
20 This guide is still available today.

21 313. Purdue also ran a series of advertisements of OxyContin in 2012 in medical  
22 journals titled “Pain vignettes,” which were styled as case studies of patients with persistent pain  
23 conditions and for whom OxyContin was recommended to improve their function.  
24

25 <sup>177</sup> Meier, *supra* note 15, at 281.

26 <sup>178</sup> *Id.* at 280.

27 <sup>179</sup> Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall Street Journal (Jan. 23, 2003,  
12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

<sup>180</sup> *Oxycontin: Its Use and Abuse*, *supra* note 157.

1           314. Purdue and Endo also sponsored and distributed a book in 2007 to promote the  
2 claim that pain relief from opioids, by itself, improved patients' function. The book remains for  
3 sale online today.

4           315. Endo's advertisements for Opana ER claimed that use of the drug for chronic pain  
5 allowed patients to perform demanding tasks like construction and portrayed Opana ER users as  
6 healthy and unimpaired.

7           316. Endo's National Initiative on Pain Control (NIPC) website also claimed in 2009  
8 that with opioids, "your level of function should improve; you may find you are now able to  
9 participate in activities of daily living, such as work and hobbies, that you were not able to enjoy  
10 when your pain was worse."

11           317. Endo further sponsored a series of CME programs through NIPC which claimed  
12 that chronic opioid therapy has been "shown to reduce pain and depressive symptoms and  
13 cognitive functioning."

14           318. Through PainKnowledge.org, Endo also supported and sponsored guidelines that  
15 stated, among other things, that "Opioid Medications are a powerful and often highly effective  
16 tool in treating pain," and that "they can help restore comfort, function, and quality of life."<sup>181</sup>

17           319. In addition, Janssen sponsored and edited patient guides which stated that  
18 "opioids may make it easier for people to live normally." The guides listed expected functional  
19 improvements from opioid use, including sleeping through the night, and returning to work,  
20 recreation, sex, walking, and climbing stairs.

21           320. Janssen also sponsored, funded, and edited a website which featured an interview  
22 edited by Janssen that described how opioids allowed a patient to "continue to function." This  
23 video is still available today.

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27 <sup>181</sup>*Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007),  
[https://www.mainequalitycounts.org/image\\_upload/Opioid%20Informed%20Consent%20Formatted\\_1\\_23\\_2008.p  
df.](https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf)

321. Furthermore, sales representatives for the Marketing Defendants communicated and continue to communicate the message that opioids will improve patients' function, without appropriate disclaimers.

322. The Marketing Defendants' statements regarding opioids' ability to improve function and quality of life are false and misleading. As the CDC's Guideline for Prescribing Opioids for Chronic Pain (the "2016 CDC Guideline" or "Guideline")<sup>182</sup> confirms, not a single study supports these claims.

323. In fact, to date, there have been no long-term studies that demonstrate that opioids are effective for treating long-term or chronic pain. Instead, reliable sources of information, including from the CDC in 2016, indicate that there is "[n]o evidence" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain."<sup>183</sup> By contrast, significant research has demonstrated the colossal dangers of opioids. The CDC, for example, concluded that "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."<sup>184</sup>

### **3. The Marketing Defendants falsely claimed doctors and patients could increase opioid usage indefinitely without added risk.**

324. The Marketing Defendants also made false and misleading statements claiming that there is no dosage ceiling for opioid treatment. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids for two reasons. First, the idea that there was no upward limit was necessary for the overarching deception that opioids are appropriate treatment for chronic pain. As discussed above, people develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Second, the dosing misrepresentation was necessary for the claim that OxyContin and competitor drugs allowed 12-hour dosing.

<sup>182</sup> 2016 CDC Guideline, *supra* note 38.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

1           325. Twelve-hour dosing is a significant marketing advantage for any medication,  
 2 because patient compliance is improved when a medication only needs to be taken twice a day.  
 3 For prescription painkillers, the 12-hour dosing is even more significant because shorter-acting  
 4 painkillers did not allow patients to get a full night's sleep before the medication wore off. A  
 5 Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is  
 6 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important  
 7 benefit."<sup>185</sup>

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 9           326. Purdue executives therefore maintained the messaging of 12-hour dosing even  
 10 when many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a  
 11 need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills.

12           327. For example, in a 1996 sales strategy memo from a Purdue regional manager, the  
 13 manager emphasized that representatives should "convinc[e] the physician that there is no need"  
 14 for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and  
 15 instead the solution is prescribing higher doses. The manager directed representatives to discuss  
 16 with physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations  
 17 in using a dose of 240mg-320mg of OxyContin."<sup>186</sup>

18           328. As doctors began prescribing OxyContin at shorter intervals in the late 1990s,  
 19 Purdue directed its sales representatives to "refocus" physicians on 12-hour dosing. One sales  
 20 manager instructed her team that anything shorter "needs to be nipped in the bud. NOW!"<sup>187</sup>

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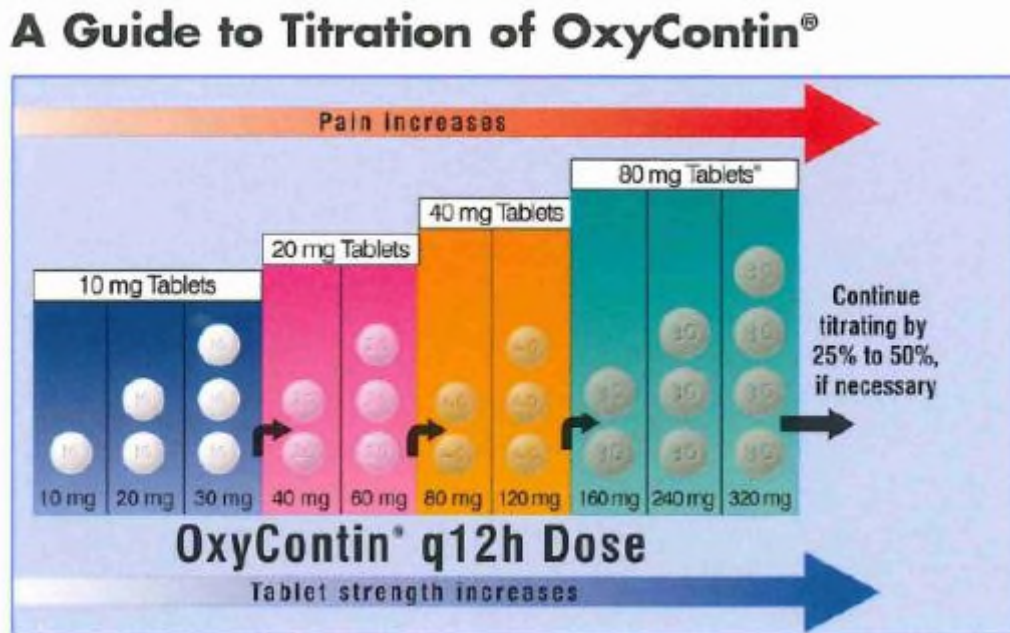

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 26 <sup>185</sup> *OxyContin launch*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>.

27 <sup>186</sup> *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on-12-hour-dosing-1996/>.

<sup>187</sup> Harriet Ryan, Lisa Girion, and Scott Glover, 'You Want a Description of Hell?' *OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

329. These misrepresentations were incredibly dangerous. As noted above, opioid dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. Notwithstanding the risks, Purdue's 2003 Conversion Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:



330. In a 2004 response letter to the FDA, Purdue tried to address concerns that patients who took OxyContin more frequently than 12 hours would be at greater risk of side effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone would not increase with more frequent dosing, and therefore no adjustments to the package labeling or 12-hour dosing regimen were needed.<sup>188</sup> But these claims were false, and Purdue's suggestion that there was no upper limit or risk associated with increased dosage was incredibly misleading.

<sup>188</sup> *Purdue Response to FDA, 2004*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/purdue-response-fda-2004/>.

331. Suggesting that it recognized the danger of its misrepresentations of no dose ceiling, Purdue discontinued the OxyContin 160 mg tablet in 2007 and stated that this step was taken “to reduce the risk of overdose accompanying the abuse of this dosage strength.”<sup>189</sup>

332. But still Purdue and the Marketing Defendants worked hard to protect their story. In March 2007, Dr. Gary Franklin, Medical Director for the Washington State Department of Labor & Industries, published the *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*. Developed in collaboration with providers in Washington State who had extensive experience in the evaluation and treatment of patients with chronic pain, the guideline recommended a maximum daily dose of opioids to protect patients.

333. In response, Purdue sent correspondence to Dr. Franklin specifically indicating, among other things, that “limiting access to opioids for persons with chronic pain is not the answer” and that the “safety and efficacy of OxyContin doses greater than 40 mg every 12 hours in patients with chronic nonmalignant pain” was well established. Purdue even went so far as to represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a patient, “this does not preclude a trial of another opioid.”

334. In 2010, Purdue published a Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin, but even the REMS does not address concerns with increasing dosage, and instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”<sup>190</sup>

<sup>189</sup> *OxyContin Tablets Risk Management Program*, Purdue Pharma L.P., <https://web.archive.org/web/20170215064438/https://www.fda.gov/ohrms/dockets/DOCKETS/07p0232/07p-0232-cp00001-03-Exhibit-02-Part-1-vol1.pdf> (revised May 18, 2007).

<sup>190</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

1           335. In 2012, APF claimed on its website that there was no “ceiling dose” for opioids  
2 for chronic pain.<sup>191</sup> APF also made this claim in a guide sponsored by Purdue, which is still  
3 available online.

4           336. Accordingly, Purdue continued to represent both publicly and privately that  
5 increased opioid usage was safe and did not present additional risk at higher doses.

6           337. Janssen also made the same misrepresentations regarding the disadvantages of  
7 dosage limits for other pain medicines in a 2009 patient education guide, while failing to address  
8 the risks of dosage increases with opioids.

9           338. Endo, on a website it sponsors, PainKnowledge.com, also made the claim in 2009  
10 that opioid dosages could be increased indefinitely.

11           339. In the “Understanding Your Pain” pamphlet discussed above, Endo assures opioid  
12 users that concern about developing tolerance to the drugs’ pain-relieving effect is “not a  
13 problem,” and that “[t]he dose can be increased” and “[y]ou won’t ‘run out’ of pain relief.”<sup>192</sup>  
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26 <sup>191</sup> Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC,  
27 [https://www.mainequalitycounts.org/image\\_upload/Noah%20Nesin%20Slides\\_Responsible%20Opioid%20Prescribing%20MCPC2.pdf](https://www.mainequalitycounts.org/image_upload/Noah%20Nesin%20Slides_Responsible%20Opioid%20Prescribing%20MCPC2.pdf) (last visited Aug. 30, 2019).

<sup>192</sup> *Understanding Your Pain: Taking Oral Opioid Analgesics*, *supra* note 167.



**ENDO**  
PHARMACEUTICALS

Toll Free: 800-623-3636  
Website: www.endo.com

**Understanding Your Pain**

**Taking Oral Opioid Analgesics**

This brochure was developed by  
Margo McCaffery, RN, MS, FAAN, and  
Chris Pearson, RN, MS, FAAN, authors of *Pain  
Clinical Manual* (2nd ed. Mosby: 1999),  
edited by Russell K. Portney, MD.

07/06 from Transitions at NUTRIS

*(How can I be sure I'm not addicted?)*

- Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

**IF I TAKE THE OPIOID NOW, WILL IT WORK LATER WHEN I REALLY NEED IT?**

Some patients with chronic pain develop tolerance. But that's not a problem.

- The dose can be increased so that even-tolerant pain can be treated.
- Tolerance's "run out" of your mind.

**WHAT CAN I DO ABOUT SIDE EFFECTS?**

Talk to your doctor, nurse, or pharmacist about the side effects of opioids. If they occur, remember that most opioid side effects can be treated or prevented.

**Constipation**

- Constipation from opioids is very common, but it can be prevented. If it does occur, it can be treated.
- Prevention is the best approach. If you take opioids daily, you need to eat more fiber and drink more liquids than you usually do. Many people also need to take a laxative. The most common type is a combination of stool softener and mild stimulant laxative. Those that can be purchased without a prescription include Peri-Colace® capsules or syrup and Senokot® tablets. Ask your pharmacist about less expensive generic forms.

**Nausea or vomiting (sickness)**

- This does not always occur, but if it does, it can be treated. Ask your doctor, nurse, or pharmacist for medicine to relieve this. After a few days the nausea usually stops.
- Try eating small and drinking slowly through a straw.
- Nausea medicines that you can buy without a prescription include Dramamine® tablets and Enervon® oral solution.
- If your pain is under good control, you may be able to reduce the nausea by taking a lower dose of opioid.

**Drowsiness (sleepiness)**

- Some degree of sleepiness would be normal when you start taking an opioid, but after a few days the drowsiness usually goes away.

340. Dosage limits with respect to opioids are particularly important not only because of the risk of addiction but also because of the potentially fatal side effect of respiratory depression. Endo's "Understanding Your Pain" pamphlet minimized this serious side effect, calling it "slowed breathing," declaring that it is "very rare" when opioids are used "appropriately," and never stating that it could be fatal:

### *"Slowed breathing"*

- ◆ The medical term for "slowed breathing" is "respiratory depression."
- ◆ This is very rare when oral opioids are used appropriately for pain relief.
- ◆ If you become so sleepy that you cannot make yourself stay awake, you may be in danger of slowed breathing. Stop taking your opioid and call your doctor immediately.

**4. The Marketing Defendants falsely instructed doctors and patients that more opioids were the solution when patients presented symptoms of addiction.**

341. Not only did the Marketing Defendants hide the serious risks of addiction associated with opioids, they actively worked to prevent doctors from taking steps to prevent or address opioid addiction in their patients.

342. One way that the Marketing Defendants worked to obstruct appropriate responses to opioid addiction was to push the concept of “pseudoaddiction.” Dr. David Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989 coining the term, which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”<sup>193</sup> (“Iatrogenic” describes a condition induced by medical treatment.) In other words, he claimed that people on prescription opioids who exhibited classic signs of addiction—“abnormal behavior”—were not addicted, but rather simply suffering from under-treatment of their pain. His solution for pseudoaddiction? More opioids.

343. Although this concept was formed based on a single case study, it proved to be a favorite trope in the Marketing Defendants’ marketing schemes. For example, using this study, Purdue informed doctors and patients that signs of addiction are actually the signs of under-treated pain which should be treated with even more opioids. Purdue reassured doctors and patients, telling them that “chronic pain has been historically undertreated.”<sup>194</sup>

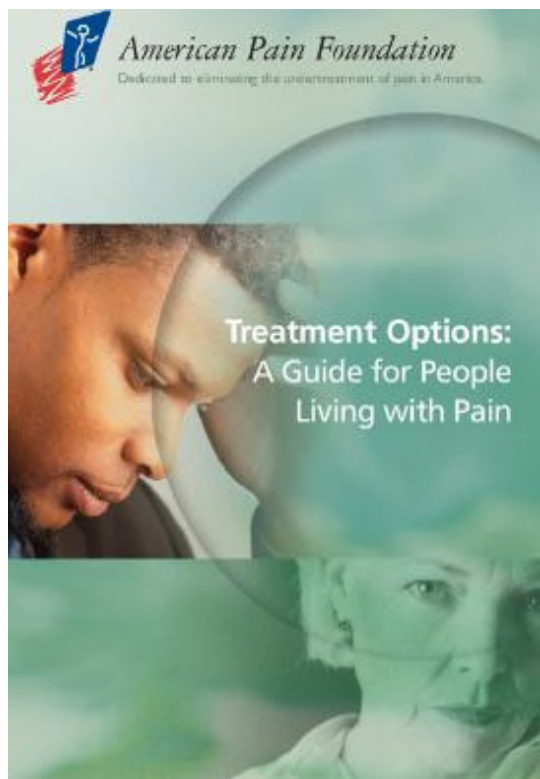
344. The Marketing Defendants continued to spread the concept of pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing, APF wrote that “[m]any pain patients (like daily coffee drinkers) claim they are ‘addicted’ when they experience withdrawal symptoms associated with physical dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain . . .”<sup>195</sup>

<sup>193</sup> David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>.

<sup>194</sup> *Oxycontin: Its Use and Abuse*, *supra* note 157.

<sup>195</sup> APF Brief Amici Curiae, *supra* note 173 at 10-11.

345. In a 2007 publication titled “Treatment Options: A Guide for People Living with Pain,” the APF claimed: “*Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted.”<sup>196</sup> In this same publication, the APF asserted that “people who are not substance abusers” may also engage in “unacceptable” behaviors such as “increasing the dose without permission or obtaining the opioid from multiple sources,” but that such behaviors do not indicate addiction and instead reflect a “desire to obtain pain relief.”<sup>197</sup>



#### Side effects

The most common side effects of opioids include constipation, nausea and vomiting, drowsiness (sleepiness), mental clouding and itching. Some people may also experience dizziness or difficulty urinating. Respiratory depression, a decreased rate and depth of breathing, is a serious side effect associated with overdose.

The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is most likely to persist. Some pain experts believe all patients started on an opioid also should be taking a stool softener or a laxative. Others believe that this treatment is appropriate only if a patient is prone to developing significant constipation because of advanced age, prior diet, other diseases, or the use of other constipating drugs. Your healthcare provider can give advice on what to eat and what medicines to use to treat constipation. Always make certain to drink plenty of fluids and be as active as possible.

If any of the other side effects don't go away, they can also be treated. Be certain to tell your provider if you are having any problems. Serious side effects such as delirium or respiratory depression can occur if the dose is increased too quickly, especially in someone who is just starting to take opioids. Tell your provider if you are unable to concentrate or think clearly after you have been taking an opioid for a few days. Report other medications you may be taking that make you sleepy. Do not drive when you first start taking these drugs or immediately after the dose has been increased. Most persons will adapt to these medicines over time and can drive safely while taking them for pain control. If side effects remain troublesome, your provider may switch you to a different opioid. The amount of pain relief can be maintained after such a switch and often the side effects can be reduced.

#### Common drugs that can cause physical dependence

- Opioids
- Stimulants
- Sedatives
- Steroids
- Certain Antidepressants
- Certain Heart Medications
- Caffeine

#### Tolerance, physical dependence and addiction

You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.

Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) if the drug is suddenly stopped or the dose is lowered too quickly. **Physical dependence is normal; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does NOT mean you are addicted.** In fact, many non-addictive drugs can produce physical dependence. To prevent withdrawal from occurring, the dose of the medication must be decreased slowly.

If you believe that you no longer need to take the opioid medication or want to reduce the dose, it is essential to speak to your provider. They will guide you on how to decrease your dose over time to prevent the experience of withdrawal.

346. Purdue published a REMS for OxyContin in 2010, and in the associated Healthcare Provider Training Guide stated that “[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.”<sup>198</sup>

347. Purdue worked, and continues to work, to create confusion about what addiction is. For example, Purdue continues to emphasize that abuse and addiction are separate and distinct

<sup>196</sup> *Treatment Options: A Guide for People Living with Pain*, *supra* note 174.

<sup>197</sup> *Id.*

<sup>198</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 190.

1 from physical dependence. Regardless of whether these statements may be technically correct,  
2 they continue to add ambiguity over the risks and benefits of opioids.

3 348. Endo sponsored an NIPC CME program in 2009 which promoted the concept of  
4 pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain.  
5 Endo substantially controlled NIPC by funding its projects, developing content, and reviewing  
6 NIPC materials.

7 349. A 2001 paper which was authored by a doctor affiliated with Janssen stated that  
8 "[m]any patients presenting to a doctor's office asking for pain medications are accused of drug  
9 seeking. In reality, most of these patients may be undertreated for their pain syndrome."<sup>199</sup>

10 350. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different  
11 from true addiction "because such behaviors can be resolved with effective pain  
12 management."<sup>200</sup>

13 351. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines  
14 pseudoaddiction as "a syndrome that causes patients to seek additional medications due to  
15 inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately,  
16 the inappropriate behavior ceases."<sup>201</sup>

23 <sup>199</sup> Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient*  
24 *and an addicted patient*, 5 *European Journal of Pain* 27-29 (2001),

<http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf>.

25 <sup>200</sup> Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By*  
26 *Misleading Doctors, Patients*, *Consumerist* (May 31, 2017, 2:05pm), [https://consumerist.com/2017/05/31/ohio-](https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/)  
27 [makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/](https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/).

<sup>201</sup> Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber*  
*Should Know Before Writing the First Prescription*, *Prescribe Responsibly*,  
[https://web.archive.org/web/20190106014101/http://www.prescriberesponsibly.com/articles/before-prescribing-](https://web.archive.org/web/20190106014101/http://www.prescriberesponsibly.com/articles/before-prescribing-opioids)  
[opioids](https://web.archive.org/web/20190106014101/http://www.prescriberesponsibly.com/articles/before-prescribing-opioids) (last modified July 2, 2015).



# What a Prescriber Should Know Before Writing the First Prescription



**TABLE 1: Definitions**

8. **Pseudoaddiction** is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.<sup>25</sup>



352. As set forth in more detail below, these statements were false and misleading as evidenced by, *inter alia*, the findings made by the CDC in 2016. Indeed, there is simply no evidence that pseudoaddiction is a real phenomenon. As research compiled by the CDC and others makes clear, pseudoaddiction is pseudoscience—nothing more than a concept Defendants seized upon to help sell more of their actually addictive drugs.

**5. The Marketing Defendants falsely claimed that risk-mitigation strategies, including tapering and abuse-deterrent technologies, made it safe to prescribe opioids for chronic use.**

353. Even when the Marketing Defendants acknowledge that opioids pose some risk of addiction, they dismiss these concerns by claiming that addiction can be easily avoided and addressed through simple steps. In order to make prescribers feel more comfortable about starting patients on opioids, the Marketing Defendants falsely communicated to doctors that certain screening tools would allow them to reliably identify patients at higher risk of addiction

1 and safely prescribe opioids, and that tapering the dose would be sufficient to manage cessation  
2 of opioid treatment. Both assertions are false.

3 354. For instance, as noted above, Purdue published a REMS for OxyContin in 2010,  
4 in which it described certain steps that needed to be followed for safe opioid use. Purdue stressed  
5 that all patients should be screened for their risk of abuse or addiction, and that such screening  
6 could curb the incidence of addiction.<sup>202</sup>

7 355. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that  
8 “[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable  
9 behaviors like increasing the dose without permission or obtaining the opioid from multiple  
10 sources, among other things. Opioids get into the hands of drug dealers and persons with an  
11 addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even  
12 from other people with pain. It is a problem in our society that needs to be addressed through  
13 many different approaches.”<sup>203</sup>

14 356. On its current website for OxyContin,<sup>204</sup> Purdue acknowledges that certain  
15 patients have higher risk of opioid addiction based on history of substance abuse or mental  
16 illness—a statement which, even if accurate, obscures the significant risk of addiction for all  
17 patients, including those without such a history, and comports with statements it has recently  
18 made that it is “bad apple” patients, and not the opioids, that are arguably the source of the  
19 opioid crisis:

20 Assess each patient’s risk for opioid addiction, abuse, or misuse prior to prescribing  
21 OxyContin, and monitor all patients receiving OxyContin for the development of these  
22 behaviors and conditions. Risks are increased in patients with a personal or family  
23 history of substance abuse (including drug or alcohol abuse or addiction) or mental  
24 illness (e.g., major depression). The potential for these risks should not, however,  
25 prevent the proper management of pain in any given patient. Patients at increased risk  
26 may be prescribed opioids such as OxyContin, but use in such patients necessitates  
27 intensive counseling about the risks and proper use of OxyContin along with intensive  
monitoring for signs of addiction, abuse, and misuse.

<sup>202</sup> *Oxycontin Risk Evaluation and Mitigation Strategy*, *supra* note 190.

<sup>203</sup> *Treatment Options: A Guide for People Living with Pain*, *supra* note 174.

<sup>204</sup> OxyContin, <https://www.oxycontin.com/index.html> (last visited Aug. 30, 2019).

357. Additionally, on its current website, Purdue refers to publicly available tools that can assist with prescribing compliance, such as patient-prescriber agreements and risk assessments.<sup>205</sup>

358. Purdue continues to downplay the severity of addiction and withdrawal and claims that dependence can easily be overcome by strategies such as adhering to a tapering schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs that “[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue OxyContin.”<sup>206</sup> And on the current OxyContin Medication Guide, Purdue also states that one should “taper the dosage gradually.”<sup>207</sup> As a general matter, tapering is a sensible strategy for cessation of treatment with a variety of medications, such as steroids or antidepressants. But the suggestion that tapering is sufficient, or simple, following chronic and continuous opioid use is misleading and dangerous, and it sets patients up for withdrawal and addiction.

359. In its “Dear Healthcare Professional” letter in 2010, Purdue instructed doctors to gradually taper someone off OxyContin to prevent signs and symptoms of withdrawal in patients who were physically dependent.<sup>208</sup> Nowhere does Purdue warn doctors or patients that tapering may be inadequate to safely end opioid treatment and avoid addiction.

360. Other Marketing Defendants make similar claims. For instance, Endo suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently active website, Opana.com, Endo states that assessment tools should be used to assess addiction risk, but that “[t]he potential for these risks should not, however, prevent proper management of pain in any given patient.”<sup>209</sup>

<sup>205</sup> *ER/LA Opioid Analgesics REMS*, Purdue, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/remis/> (last visited Mar. 7, 2019).

<sup>206</sup> Oxycontin.com, *supra* note 204.

<sup>207</sup> *OxyContin Full Prescribing Information*, Purdue Pharma LP, <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o> (last visited Aug. 30, 2019).

<sup>208</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 190.

<sup>209</sup> Opana ER, Endo Pharmaceuticals, Inc., <http://www.opana.com> (last visited Aug. 30, 2019).



1           361. On the same website, Endo makes similar statements about tapering, stating  
2 “[w]hen discontinuing OPANA ER, gradually taper the dosage.”<sup>210</sup>

3           362. Janssen also states on its currently active website, PrescribeResponsibly.com, that  
4 the risk of opioid addiction “can usually be managed” through tools such as “opioid agreements”  
5 between patients and doctors.<sup>211</sup>

6           363. Each Marketing Defendant’s statements about tapering misleadingly implied that  
7 gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking  
8 opioids.

9           364. The Marketing Defendants have also made and continue to make false and  
10 misleading statements about the purported abuse-deterrent properties of their opioid pills to  
11 suggest these reformulated pills are not susceptible to abuse. In so doing, the Marketing  
12 Defendants have increased their profits by selling more pills for substantially higher prices.

13           365. For instance, since at least 2001, Purdue has contended that “abuse resistant  
14 products can reduce the incidence of abuse.”<sup>212</sup> Until recently, Purdue’s website touted abuse-  
15 deterrent properties by saying they “can make a difference.”<sup>213</sup>

16           366. On August 17, 2015, Purdue announced the launch of a new website, “Team  
17 Against Opioid Abuse,” which it said was “designed to help healthcare professionals and  
18 laypeople alike learn about different abuse-deterrent technologies and how they can help in the  
19 reduction of misuse and abuse of opioids.”<sup>214</sup> This website appears to no longer be active.

20           367. A 2013 study which was authored by at least two doctors who at one time  
21 worked for Purdue stated that “[a]buse-deterrent formulations of opioid analgesics can reduce  
22

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23 <sup>210</sup> *Id.*

24 <sup>211</sup> Heit & Gourlay, *supra* note 201.

25 <sup>212</sup> *Oxycontin: Its Use and Abuse*, *supra* note 157.

26 <sup>213</sup> *Opioids with Abuse-Deterrent Properties*, Purdue, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last visited May 16, 2018); *see also* <https://web.archive.org/web/20180302203422/http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/>.

27 <sup>214</sup> *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015), <https://web.archive.org/web/20170404120618/http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/>.

1 abuse.”<sup>215</sup> In another study from 2016 with at least one Purdue doctor as an author, the authors  
 2 claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent  
 3 formulations were introduced.<sup>216</sup>

4 368. Interestingly, one report found that the original safety label for OxyContin, which  
 5 instructed patients not to crush the tablets because it would have a rapid release effect, may have  
 6 inadvertently given opioid users ideas for techniques to get high from these drugs.<sup>217</sup>

7 369. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula  
 8 with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation  
 9 from users to snort or inject it. But the following year, the FDA concluded:

10 While there is an increased ability of the reformulated version of Opana ER to resist  
 11 crushing relative to the original formulation, study data show that the reformulated  
 12 version’s extended-release features can be compromised when subjected to other  
 13 forms of manipulation, such as cutting, grinding, or chewing, followed by  
 14 swallowing.

15 Reformulated Opana ER can be readily prepared for injection, despite Endo’s claim  
 16 that these tablets have “resistance to aqueous extraction (i.e., poor syringeability).”  
 17 It also appears that reformulated Opana ER can be prepared for snorting using  
 18 commonly available tools and methods.

19 The postmarketing investigations are inconclusive, and even if one were to treat  
 20 available data as a reliable indicator of abuse rates, one of these investigations also  
 21 suggests the troubling possibility that a higher percentage of reformulated Opana  
 22 ER abuse is via injection than was the case with the original formulation.<sup>218</sup>

23 370. Despite the FDA’s determination that the evidence did not support Endo’s claims  
 24 of abuse-deterrence, Endo advertised its reformulated pills as “crush resistant” and directed its  
 25 sales representatives to represent the same to doctors. Endo improperly marketed Opana ER as

26 <sup>215</sup> Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in*  
 27 *oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release*  
*oxycodone with abuse-deterrent characteristics*, 22 (12) *Pharmacoepidemiol Drug Saf.* 1274-82 (Sept. 30, 2013),  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/>.

<sup>216</sup> Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh  
 Hari Krishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterrent opioid formulation*  
*(OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 *Clin. Pharmacol. Ther.*, 275-86  
 (June 22, 2016), <http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full>.

<sup>217</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 37.

<sup>218</sup> *FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Admin. (May 10, 2013),  
<https://wayback.archive-it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm>.

1 crush-resistant, when Endo's own studies showed that the pill could be crushed and ground. In  
 2 2016, Endo reached an agreement with the Attorney General of the State of New York that  
 3 required Endo to discontinue making such statements.<sup>219</sup>

4 371. Mallinckrodt likewise promoted its branded opioids, Exalgo and Xartemis XR, as  
 5 having abuse-deterrent properties, even though the FDA did not approve ADF labeling for either  
 6 drug. For both Exalgo and Xartemis XR, Mallinckrodt trained its sales representatives to tell  
 7 doctors that the pills were tamper-resistant in that they were harder to crush and to inject, and  
 8 that the drugs were less likely to provide euphoria to users. Mallinckrodt pushed its branded  
 9 products as solutions to rampant opioid abuse while continuing to profit from the high rate of  
 10 abuse of its generics.

11 372. The Marketing Defendants' assertions that their reformulated pills could curb  
 12 abuse and that other risk-mitigation strategies enabled doctors to safely prescribe high doses of  
 13 long-acting opioids were false and misleading.

14 373. Ultimately, even if a physician prescribes opioids after screening for abuse risk,  
 15 advising a patient to taper, and selecting brand-name, abuse-deterrent formulations, chronic and  
 16 continuous opioid use still comes with significant risks of addiction and abuse. The Marketing  
 17 Defendants' statements to the contrary were designed to create a false sense of security and  
 18 assure physicians that they could safely prescribe potent narcotics to their patients.

19 **F. Research Demonstrates that the Manufacturing Defendants' Claims are False.**

20 374. Contrary to the Manufacturing Defendants' misrepresentations about the benefits  
 21 and risks of opioids, growing evidence suggests that using opioids to treat chronic pain leads to  
 22 overall negative outcomes, delaying or preventing recovery and providing little actual relief, all  
 23 while presenting serious risks of overdose.

24  
 25  
 26 <sup>219</sup> Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement with Endo*  
 27 *Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs* (Mar. 3, 2016),  
<https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>.

375. For example, Dr. Gary Franklin, Medical Director of the Washington State Department of Labor and Industries (“L&I”), together with its chief pharmacist, Jaymie Mai, conducted a thorough analysis of all recorded deaths in the state’s workers’ comp system. They published their findings in the *American Journal of Industrial Medicine* in 2005 and again in 2012.<sup>220</sup>

376. Their research showed that the total number of opioid prescriptions paid for by the Workers’ Compensation Program tripled between 1996 and 2006.<sup>221</sup> Not only did the number of prescriptions balloon, so too did the doses; from 1996 to 2002 the mean daily morphine equivalent dose (“MED”) nearly doubled, and remained that way through 2006.<sup>222</sup> As injured workers were given more prescriptions of higher doses of opioids, the rates of opioid overdoses among that population jumped, from zero in 1996 to more than twenty in 2005. And in 2009, over thirty people receiving opioid prescriptions through the workers’ compensation program died of an opioid overdose.<sup>223</sup>

377. Additional research from L&I demonstrates that the use of opioids to treat pain after an injury actually prevents or slows a patient’s recovery. In a study of employees who had suffered a low back injury on the job, Dr. Franklin determined that among those who were prescribed opioids soon after the injury, employees who were given high doses of opioids, or for periods of more than a week, were far more likely to experience negative health outcomes than the employees who were given smaller doses or for a shorter term.

378. Specifically, the study showed that, after adjusting for the baseline covariates, injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain disabled a year later than workers

<sup>220</sup> Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith A. Turner, Ph.D., Deborah Fulton-Kehoe, Ph.D., MPH, and Linda Grant, BSN, MBA, *Opioid dosing trends and mortality in Washington State Workers’ Compensation, 1996-2002*, 48 Am J Ind Med 91-99 (2005).

<sup>221</sup> Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith Turner, Ph.D., Mark Sullivan, M.D., Ph.D., Thomas Wickizer, Ph.D., and Deborah Fulton-Kehoe, Ph.D., *Bending the Prescription Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline*, 55 Am J Ind Med 325, 327 (2012).

<sup>222</sup> *Id.* at 327-28.

<sup>223</sup> *Id.* at 328.

1 with similar injuries who received no opioids at all. Similarly, those who received two  
 2 prescriptions of opioids for the injury were 1.8 times more likely to remain disabled a year after  
 3 their injury than workers who received no opioids at all, and those receiving daily doses higher  
 4 than 150 MED were more than twice as likely to be on disability a year later, compared to  
 5 workers who received no opioids.<sup>224</sup>

6 379. In sum, not only do prescription opioids present significant risks of addiction and  
 7 overdose, but they also hinder patient recovery after an injury. This dynamic presents problems  
 8 for employers, too, who bear significant costs when their employees do not recover quickly from  
 9 workplace injuries. Employers are left without their labor force and may be responsible for  
 10 paying for the injured employee's disability for long periods of time.

11 **G. The 2016 CDC Guideline and Other Recent Analyses Confirm That the Marketing**  
 12 **Defendants' Statements About the Risks and Benefits of Opioids Are Patently False.**

13 380. Contrary to the statements made by the Marketing Defendants in their well-  
 14 orchestrated campaign to tout the benefits of opioids and downplay their risks, recent studies  
 15 confirm the Marketing Defendants' statements were false and misleading.

16 381. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March  
 17 15, 2016.<sup>225</sup> The 2016 CDC Guideline, approved by the FDA, "provides recommendations for  
 18 primary care clinicians who are prescribing opioids for chronic pain outside of active cancer  
 19 treatment, palliative care, and end-of-life care." The Guideline also assesses the risks and harms  
 20 associated with opioid use.

21 382. The 2016 CDC Guideline is the result of a thorough and extensive process by the  
 22 CDC. The CDC issued the Guideline after it "obtained input from experts, stakeholders, the  
 23 public, peer reviewers, and a federally chartered advisory committee." The recommendations in  
 24

25 <sup>224</sup> Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early opioid prescription and*  
 26 *subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine  
 199, 201-202.

27 <sup>225</sup> 2016 CDC Guideline, *supra* note 38.

1 the 2016 CDC Guideline were further made “on the basis of a systematic review of the best  
2 available evidence . . .”

3 383. The CDC went through an extensive and detailed process to solicit expert  
4 opinions for the Guideline:

5 CDC sought the input of experts to assist in reviewing the evidence and providing  
6 perspective on how CDC used the evidence to develop the draft recommendations.  
7 These experts, referred to as the “Core Expert Group” (CEG) included subject  
8 matter experts, representatives of primary care professional societies and state  
9 agencies, and an expert in guideline development methodology. CDC identified  
10 subject matter experts with high scientific standing; appropriate academic and  
11 clinical training and relevant clinical experience; and proven scientific excellence  
12 in opioid prescribing, substance use disorder treatment, and pain management.  
13 CDC identified representatives from leading primary care professional  
14 organizations to represent the audience for this guideline. Finally, CDC identified  
15 state agency officials and representatives based on their experience with state  
16 guidelines for opioid prescribing that were developed with multiple agency  
17 stakeholders and informed by scientific literature and existing evidence-based  
18 guidelines.

19 384. The 2016 Guideline was also peer-reviewed pursuant to “the final information  
20 quality bulletin for peer review.” Specifically, the Guideline describes the following independent  
21 peer-review process:

22 [P]eer review requirements applied to this guideline because it provides influential  
23 scientific information that could have a clear and substantial impact on public- and  
24 private-sector decisions. Three experts independently reviewed the guideline to  
25 determine the reasonableness and strength of recommendations; the clarity with  
26 which scientific uncertainties were clearly identified; and the rationale, importance,  
27 clarity, and ease of implementation of the recommendations. CDC selected peer  
reviewers based on expertise, diversity of scientific viewpoints, and independence  
from the guideline development process. CDC assessed and managed potential  
conflicts of interest using a process similar to the one as described for solicitation  
of expert opinion. No financial interests were identified in the disclosure and review  
process, and nonfinancial activities were determined to be of minimal risk; thus, no  
significant conflict of interest concerns were identified.

385. The findings in the 2016 CDC Guideline both confirmed the existing body of  
scientific evidence regarding the questionable efficacy of opioid use and contradicted  
Defendants’ statements about opioids.

1           386. For instance, the Guideline states “[e]xtensive evidence shows the possible harms  
2 of opioids (including opioid use disorder, overdose, and motor vehicle injury)” and that “[o]pioid  
3 pain medication use presents serious risks, including overdose and opioid use disorder.” The  
4 Guideline further confirms there are significant symptoms related to opioid withdrawal,  
5 including drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating,  
6 tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant  
7 women, and the unmasking of anxiety, depression, and addiction. These findings contradict  
8 statements made by Defendants regarding the minimal risks associated with opioid use,  
9 including that the risk of addiction from chronic opioid use is low.

10           387. The Guideline also concludes that there is “[n]o evidence” to show “a long-term  
11 benefit of opioids in pain and function versus no opioids for chronic pain . . .” Furthermore, the  
12 Guideline indicates that “continuing opioid therapy for 3 months substantially increases the risk  
13 of opioid use disorder.” Indeed, the Guideline indicates that “[p]atients who do not experience  
14 clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with  
15 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in  
16 order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids”  
17 because the patient is “not receiving a clear benefit.” These findings flatly contradict claims  
18 made by the Defendants that there are minimal or no adverse effects of long-term opioid use, or  
19 that long-term opioid use could actually improve or restore a patient’s function.

20           388. In support of these statements about the lack of long-term benefits of opioid use,  
21 the CDC concluded that “[a]lthough opioids can reduce pain during short-term use, the clinical  
22 evidence review found insufficient evidence to determine whether pain relief is sustained and  
23 whether function or quality of life improves with long-term opioid therapy.” The CDC further  
24 found that “evidence is limited or insufficient for improved pain or function with long-term use  
25 of opioids for several chronic pain conditions for which opioids are commonly prescribed, such  
26 as low back pain, headache, and fibromyalgia.”  
27



1           389. With respect to opioid dosing, the Guideline reports that “[b]enefits of high-dose  
2 opioids for chronic pain are not established” while the “risks for serious harms related to opioid  
3 therapy increase at higher opioid dosage.” The CDC specifically explains that “there is now an  
4 established body of scientific evidence showing that overdose risk is increased at higher opioid  
5 dosages.” The CDC also states that there is an “increased risk[] for opioid use disorder,  
6 respiratory depression, and death at higher dosages.” As a result, the CDC advises doctors to  
7 “avoid increasing dosage” above 90 MME per day. These findings contradict statements made  
8 by Defendants that increasing dosage is safe and that under-treatment is the cause for certain  
9 patients’ aberrant behavior.

10           390. The 2016 CDC Guideline also contradicts statements made by Defendants that  
11 there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the  
12 Guideline indicates that available risk screening tools “show insufficient accuracy for  
13 classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that  
14 doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid  
15 therapy.”

16           391. Finally, the 2016 CDC Guideline states that “[n]o studies” support the notion that  
17 “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,”  
18 noting that the technologies—even when they work—“do not prevent opioid abuse through oral  
19 intake, the most common route of opioid abuse, and can still be abused by nonoral routes.” In  
20 particular, the CDC found as follows:

21           The “abuse-deterrent” label does not indicate that there is no risk for abuse. No  
22 studies were found in the clinical evidence review assessing the effectiveness of  
23 abuse-deterrent technologies as a risk mitigation strategy for deterring or  
24 preventing abuse. In addition, abuse-deterrent technologies do not prevent  
unintentional overdose through oral intake. Experts agreed that recommendations  
could not be offered at this time related to use of abuse-deterrent formulations.

25           Accordingly, the CDC’s findings regarding “abuse-deterrent technologies” directly contradict  
26 Purdue and Endo’s claims that their new pills deter or prevent abuse.

392. Notably, in addition to the findings made by the CDC in 2016, the Washington State Agency Medical Directors' Group (AMDG)—a collaboration among several Washington State Agencies—published its *Interagency Guideline on Prescribing Opioids for Pain* in 2015. The AMDG came to many of the same conclusions as the CDC did. For example, the AMDG found that “there is little evidence to support long term efficacy of [chronic opioid analgesic therapy, or “COAT”] in improving function and pain, [but] there is ample evidence of its risk for harm . . . .”<sup>226</sup>

393. In addition, as discussed above, in contrast to Defendants' statements that the 1980 Porter and Jick letter provided evidence of the low risk of opioid addiction in pain patients, the NEJM recently published a letter largely debunking the use of the Porter and Jick letter as evidence for such a claim.<sup>227</sup> The researchers demonstrated how the Porter and Jick letter was irresponsibly cited and, in some cases, “grossly misrepresented,” when in fact it did not provide evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for pain. As noted above, Dr. Jick reviewed only files of patients administered opioids in a hospital setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

394. The authors of the 2017 letter described their methodology as follows:

We performed a bibliometric analysis of this [1980] correspondence from its publication until March 30, 2017. For each citation, two reviewers independently evaluated the portrayal of the article's conclusions, using an adaptation of an established taxonomy of citation behavior along with other aspects of generalizability . . . . For context, we also ascertained the number of citations of other stand-alone letters that were published in nine contemporaneous issues of the *Journal* (in the index issue and in the four issues that preceded and followed it).

We identified 608 citations of the index publication and noted a sizable increase after the introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 . . . . **Of the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription, whereas some authors grossly**

<sup>226</sup> *Interagency Guideline on Prescribing Opioids for Pain*, Agency Med. Directors' Group (June 2015), <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>.

<sup>227</sup> Leung, et al., *supra* note 147.

1 **misrepresented the conclusions of the letter** . . . Of note, affirmational citations  
2 have become much less common in recent years. In contrast to the 1980  
3 correspondence, 11 stand-alone letters that were published contemporaneously by  
the Journal were cited a median of 11 times.<sup>228</sup> (Emphasis added).

4 395. The researchers provided examples of quotes from articles citing the 1980 letter  
5 and noted several shortcomings and inaccuracies with the quotations. For instance, the  
6 researchers concluded that these quotations (i) “overstate[] conclusions of the index publication,”  
7 (ii) do[] not accurately specify its study population,” and (iii) did not adequately address  
8 “[l]imitizations to generalizability.”<sup>229</sup>

25 <sup>228</sup> *Id.* (emphasis added).

26 <sup>229</sup> Supplementary Appendix to Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B.  
27 Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of  
Opioid Addiction*, 376 New Eng. J. Med. 2194-95 (June 1, 2017),  
<https://www.nejm.org/doi/full/10.1056/NEJMc1700150>.

Quote	Reference	Comment
"This pain population with no abuse history is literally at no risk for addiction."	Kowal N. What is the issue?: pseudoaddiction or undertreatment of pain. Nurs Econ 1998;17(6):348-9	
"In truth, however, the medical evidence overwhelmingly indicates that properly administered opioid therapy rarely if ever results in "accidental addiction" or "opioid abuse"."	Libby RT. Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Painkillers. The Independent Review 2006;10(4):511-545.	
"Fear of addiction may lead to reluctance by the physician to prescribe. [...] However, there is no evidence that this occurs when prescribing opioids for pain."	Iles S, Catterall JR, Hanks G. Use of opioid analgesics in a patient with chronic abdominal pain. Int J Clin Pract 2002;56(3):227-8.	
"In reality, medical opioid addiction is very rare. In Porter and Jick's study on patients treated with narcotics, only four of the 11,882 cases showed psychological dependency."	Liu W, Xie S, Yue L, et al. Investigation and analysis of oncologists' knowledge of morphine usage in cancer pain treatment. Onco Targets Ther 2014;7:729-37.	Overstates conclusions of the index publication does not accurately specify its study population. Limitations to generalizability are not otherwise explicitly mentioned.
"Physicians are frequently concerned about the potential for addiction when prescribing opiates; however, there have been studies suggesting that addiction rarely evolves in the setting of painful conditions."	Curtis LA, Morrell TD, Todd KH. Pain Management in the Emergency Department 2006;8(7).	
"Although medicine generally regards anecdotal information with disdain (rigorously controlled double-blind clinical trials are the "gold standard"), solid data on the low risk of addiction to opioid analgesics and the manageability of adverse side effects have been ignored or discounted in favor of the anecdotal, the scientifically unsupported, and the clearly fallacious."	Rich BA. Prioritizing pain management in patient care. Has the time come for a new approach. Postgrad Med 2001;110(3):15-7.	
"The Boston Drug Surveillance Program reviewed the charts of nearly 12,000 cancer pain patients treated over a decade and found only four of them could be labeled as addicts."	Levy MH. Pharmacologic management of cancer pain. Semin Oncol 1994;21(5):718-39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

396. Based on this review, the researchers concluded as follows:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. Our findings highlight the potential

1 consequences of inaccurate citation and underscore the need for diligence when  
2 citing previously published studies.<sup>230</sup>

3 397. These researchers' careful analysis demonstrates the falsity of Defendants' claim  
4 that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting  
5 this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth,  
6 with blatant disregard for the consequences of their misrepresentations.

7 **H. Spokane Has Been Directly Affected by the Opioid Epidemic Caused by Defendants.**

8 398. The City of Spokane, the second largest city in Washington, is located in eastern  
9 Washington State and has over 220,000 residents.

10 399. Much like the rest of the United States, Spokane has felt the profound  
11 consequences of the opioid epidemic. As a direct result of Defendants' aggressive marketing  
12 scheme and failure to stop the flood of prescription opioids, Spokane has suffered significant and  
13 ongoing harms—harms that will continue well into the future. Each day that Defendants continue  
14 to evade responsibility for the epidemic they caused, the City must continue allocating  
15 substantial resources to address it.

16 400. Opioid use has reached crisis levels across the country, and Spokane is not  
17 immune to national trends. Statistics regarding opioid overdoses and treatment opioid-use  
18 disorder—while not capturing the whole story of this far-reaching epidemic—provide  
19 quantitative indicators of the extent of the crisis. In Spokane County, where the City of Spokane  
20 is located, the statistics show that, in recent years, the crisis has only grown. For example,  
21 between 2002-2004 and 2011-2013, the number of opioid-use treatment admissions rose  
22  
23  
24  
25  
26

27 <sup>230</sup> Leung, et al., *supra* note 147.

188.1%.<sup>231</sup> From 2008 to 2010, there were 142 opioid-related deaths in Spokane County;<sup>232</sup> this grim count increased to 215 opioid-related deaths between 2012 and 2016.<sup>233</sup>

401. From one year to the next, the death toll has steadily climbed. In 2014, 36 people in Spokane County died from opioid-related overdoses; in 2015, 64 people died from overdoses that involved at least one opioid—a 78% increase.<sup>234</sup>

402. As with much of the rest of the United States, heroin use is on the rise. In Washington, while heroin was involved in only 14 percent of opioid-related deaths in 2010, it was involved in nearly half of opioid-related deaths in 2015.<sup>235</sup> In Spokane County, heroin was also involved in nearly half of opioid-related deaths in 2015.<sup>236</sup>

403. The high rates of overdoses and opioid-related deaths in the City are a direct result of the significant flow of opioids into Spokane County. In 2014, for example, there were 213,845 prescriptions dispensed in Spokane County.

404. Because Spokane's youth are also caught up in the opioid epidemic, the City will feel its consequences for decades to come. In 2016, for example, one out of every twenty high school students in Spokane County reported using prescription opioids to get high in the last 30 days. In 2010, this rate was even higher, with nearly 10% of high school students reporting that they had used prescription opioids recreationally within the last 30 days.

405. Spokane has been working to confront the emergency caused by Defendants' reckless promotion and distribution of prescription opioids. For 2019, the total of all City budgets is \$1 billion, and it has spent hundreds of millions of dollars in the past and will continue

<sup>231</sup> *Opioid Trends Across Washington State*, U. of Wash. Alcohol & Drug Abuse Inst. (Apr. 2015) <http://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf>

<sup>232</sup> *Prescription Opiates and Heroin – Spokane County*, U. of Wash. Alcohol & Drug Abuse Inst. [http://www.adai.uw.edu/wastate/opiates/spokane\\_opiates\\_2010.pdf](http://www.adai.uw.edu/wastate/opiates/spokane_opiates_2010.pdf) (last visited June 19, 2018).

<sup>233</sup> *Opioid-related Deaths in Washington State, 2006-2016*, Wash. St. Dep't of Health, (May 2017), <https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf>.

<sup>234</sup> Rachel Alexander, "Opioid overdose deaths in Spokane County up 78 percent last year." *The Spokesman-Review* (Dec. 14, 2016), <http://www.spokesman.com/stories/2016/dec/14/opioid-overdose-deaths-in-spokane-county-up-78-per/#/0>.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*



1 to spend substantial sums in the future to address the epidemic. The costs and harms described  
2 in the following sections are illustrative but not exhaustive examples of the significant burden the  
3 opioid crisis has imposed on the City.

4 **1. The criminal justice system has incurred substantial costs in responding to**  
5 **the epidemic caused by Defendants.**

6 406. Spokane's Police Department ("SPD") provides law enforcement services to the  
7 City. SPD protects the public, provides law enforcement services within the City, and is  
8 dedicated to making Spokane safe.

9 407. SPD expends enormous resources fulfilling its critical missions. A significant  
10 portion of those resources are devoted to addressing and responding to the crisis caused by  
11 Defendants, including investigating opioid-related crimes.

12 408. SPD encounters persons affected by opioid use and abuse daily. Police officers  
13 commonly encounter persons in possession of opioids. As opioid overdoses are now a common  
14 occurrence, officers carry naloxone. SPD has expended resources training its officers both to  
15 administer naloxone and to safely handle fentanyl, which can be lethal in miniscule amounts and  
16 can be absorbed through the skin.

17 409. Further, officers are exposed to syringes and needles on the job. Used needles and  
18 uncapped syringes are both a public health hazard and officer safety hazard.

19 410. The City's court system also commonly sees defendants charged with opioid-  
20 related offenses, and there has been a rise in criminal cases related to opioids over the past  
21 decade. In particular, there has been a marked increase in property and theft crimes that are  
22 driven by opioid addiction. Opioids also play a role in other types of cases in which the charges  
23 do not directly involve controlled substances. Both the Office of the Spokane City Prosecuting  
24 Attorney and the City of Spokane Public Defender's Office have seen an increase in criminal  
25 cases related to opioids, and Spokane has had to spend significant resources to prosecute crimes  
26 and has incurred greater costs in its staffing to do so.



1           **2. The opioid crisis has had additional impacts on the City, including its**  
 2           **emergency services and parks.**

3           411. Spokane Fire Department (“SFD”) provides essential emergency medical and life-  
 4 saving services. As the first responders to overdoses, deaths, and injuries related to opioid abuse,  
 5 SFD is at the front line of the opioid crisis. Both in terms of responding to these emergencies and  
 6 in training and preparing for them, SFD has incurred costs as a result of Defendants’ conduct.  
 7 SFD has experienced an increased call volume for possible opioid overdoses. To be able to  
 8 respond to opioid overdoses, SFD personnel now carry naloxone. SFD has spent resources  
 9 training its personnel to administer naloxone.

10          412. Another effect of the opioid epidemic in Spokane is the increase in the City’s  
 11 homeless population, which has grown in recent years. Although the causes of homelessness are  
 12 multi-faceted and complex, opioid abuse is both a contributing cause and result of homelessness.  
 13 Opioid-use disorder is also a significant factor that prevents someone from maintaining  
 14 economic well-being and housing stability.

15          413. According to the annual Point-In-Time Count, the number of homeless persons  
 16 grew 5.8 percent from 2013 to 2017. In 2013, there were 1,030 homeless households.<sup>237</sup> In 2017,  
 17 there were 1,090 homeless households in Spokane County.<sup>238</sup>

18          414. The Parks & Recreation Department is also affected by the opioid crisis. For  
 19 example, used syringes are frequently found in parks and other public places, including in  
 20 homeless encampments. The City expends resources to safely dispose of used needles and  
 21 syringes left in public places. Sharps containers have also been installed in some bathrooms and  
 22 other public locations. Individuals within the Parks Department are trained to properly dispose of  
 23 needles.

24  
 25  
 26 <sup>237</sup> 2013 Point in Time Count, Wash. Dep’t of Commerce (Jan. 2013), <http://www.commerce.wa.gov/wp-content/uploads/2016/10/hau-pit-final-summary-2013.pdf>.

27 <sup>238</sup> 2017 Point in Time Count, Wash. Dep’t of Commerce (Aug. 2017), <http://www.commerce.wa.gov/wp-content/uploads/2017/12/CSHD-HAU-2017-County-Summary-August-2017v2.pdf>.

**I. No Federal Agency Action, Including by the FDA, Can Provide the Relief Spokane Seeks Here.**

415. The injuries Spokane has suffered and will continue to suffer cannot be addressed by agency or regulatory action. There are no rules the FDA could make or actions the agency could take that would provide Spokane the relief it seeks in this litigation.

416. Even if prescription opioids were entirely banned today or only used for the intended purpose, millions of Americans, including Spokane residents, would remain addicted to opioids, and overdoses will continue to claim lives.

417. Regulatory action would do nothing to compensate the City for the money and resources it has already expended addressing the impacts of the opioid epidemic and the resources it will need in the future. Only this litigation has the ability to provide the City with the relief it seeks.

418. Furthermore, the costs Spokane has incurred in responding to the opioid crisis and in rendering public services described above are recoverable pursuant to the causes of actions raised by the City. Defendants' misconduct alleged herein is not a series of isolated incidents, but instead the result of a sophisticated and complex marketing scheme over the course of more than twenty years that has caused a substantial and long-term burden on the municipal services provided by the City. In addition, the public nuisance created by Defendants and the City's requested relief in seeking abatement further compels Defendants to reimburse and compensate Spokane for the substantial resources it has expended to address the opioid crisis.

**V. CLAIMS FOR RELIEF**  
**COUNT ONE — VIOLATIONS OF THE WASHINGTON CONSUMER PROTECTION ACT, RCW 19.86, *ET SEQ.***

419. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

420. The Washington Consumer Protection Act is codified at RCW 19.86 *et seq.* (CPA). The CPA establishes a comprehensive framework for redressing the violations of applicable law, and municipalities of Washington State like Spokane can enforce the CPA and

1 recover damages. RCW 19.86.090. The conduct at issue in this case falls within the scope of the  
2 CPA.

3 421. The CPA prohibits unfair methods of competition and unfair or deceptive acts or  
4 practices in the conduct of any trade or commerce. Defendants engaged and continue to engage  
5 in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct  
6 pursuant to a common practice of misleading the public regarding the purported benefits and  
7 risks of opioids.

8 422. The Manufacturing Defendants, at all times relevant to this Complaint, directly  
9 and/or through their control of third parties, violated the CPA by making unfair and/or deceptive  
10 representations about the use of opioids to treat chronic and non-cancer pain, including to  
11 physicians and consumers in Spokane. Each Manufacturing Defendant also omitted or concealed  
12 material facts and failed to correct prior misrepresentations and omissions about the purported  
13 benefits and risks of opioids. In addition, each Manufacturing Defendant's silence regarding the  
14 full risks of opioid use constitutes deceptive conduct prohibited by the CPA.

15 423. The Distributor Defendants, at all times relevant to this Complaint, directly and/or  
16 through their control of third parties, violated the CPA by making unfair and/or deceptive  
17 representations about their compliance with their obligations to maintain effective controls  
18 against diversion of prescription opioids and to report suspicious orders. The Distributor  
19 Defendants concealed the extent of their opioid distribution in order to avoid the issuance of  
20 restrictive quotas, and manipulated the political process to shield themselves from enforcement  
21 actions that would have stopped shipments of opioids.

22 424. These unfair methods of competition and unfair and/or deceptive acts or practices  
23 in the conduct of trade or commerce were reasonably calculated to deceive Spokane and its  
24 consumers, and did in fact deceive the City and its consumers. Each Manufacturing Defendant's  
25 misrepresentations, concealments, and omissions continue to this day.

26 425. As a result of Defendants' misrepresentations, Spokane has spent substantial sums  
27 of money on increased law enforcement, public safety, and other human services.

1           426. But for these unfair methods of competition and unfair and/or deceptive acts or  
2 practices in the conduct of trade or commerce, Spokane would not have incurred the substantial  
3 costs related to the epidemic caused by Defendants.

4           427. Logic, common sense, justice, policy, and precedent indicate Manufacturing  
5 Defendants' unfair and deceptive conduct has caused the damage and harm complained of  
6 herein. Manufacturing Defendants knew or reasonably should have known that their statements  
7 regarding the risks and benefits of opioids were false and misleading, and that their statements  
8 were causing harm from their continued production and marketing of opioids. The Distributor  
9 Defendants knew or reasonably should have known that the proliferation of prescription opioids  
10 was causing damage to the City. Thus, the harms caused by Defendants' unfair and deceptive  
11 conduct to Spokane were reasonably foreseeable, including the financial and economic losses  
12 incurred by the City.

13           428. Furthermore, Spokane brings this cause of action in its sovereign capacity for the  
14 benefit of the State of Washington. The CPA expressly authorizes local governments to enforce  
15 its provisions and to recover damages for violations of the CPA, and this action is brought to  
16 promote the public welfare of the state and for the common good of the state.

17           429. As a direct and proximate cause of each Defendant's unfair and deceptive  
18 conduct, (i) Spokane has sustained and will continue to sustain injuries, and (ii) pursuant to  
19 RCW 19.86.090, Spokane is entitled to actual and treble damages in amounts to be determined at  
20 trial, attorneys' fees and costs, and all other relief available under the CPA.

21           430. The Court should also grant injunctive relief enjoining Defendants from future  
22 violations of the CPA. Defendants' actions, as complained of herein, constitute unfair  
23 competition or unfair, deceptive, or fraudulent acts or practices in violation of the CPA.

## 24                                   **COUNT TWO — PUBLIC NUISANCE**

25           431. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
26 fully set forth herein.

1           432. Pursuant to RCW 7.48.010, an actionable nuisance is defined as, *inter alia*,  
2 “whatever is injurious to health or indecent or offensive to the senses . . .”

3           433. Pursuant to RCW 7.48.130, “A public nuisance is one which affects equally the  
4 rights of an entire community or neighborhood, although the extent of the damage may be  
5 unequal.”

6           434. Spokane and its residents have a right to be free from conduct that endangers their  
7 health and safety. Yet Defendants have engaged in conduct which endangers or injures the health  
8 and safety of the residents of the City by their production, promotion, distribution, and marketing  
9 of opioids for use by residents of Spokane and in a manner that substantially interferes with the  
10 welfare of Spokane.

11           435. Each Defendant has created or assisted in the creation of a condition that is  
12 injurious to the health and safety of Spokane and its residents, and interferes with the  
13 comfortable enjoyment of life and property of entire communities and/or neighborhoods in the  
14 City.

15           436. Defendants’ conduct has directly caused deaths, serious injuries, and a severe  
16 disruption of the public peace, order and safety, including fueling the homeless and heroin crises  
17 facing the City described herein. Defendants’ conduct is ongoing and continues to inflict long-  
18 lasting harms on the City.

19           437. The health and safety of the residents of Spokane, including those who use, have  
20 used, or will use opioids, as well as those affected by users of opioids, are matters of substantial  
21 public interest and of legitimate concern to the City’s citizens and its residents.

22           438. Defendants’ conduct has affected and continues to affect a substantial number of  
23 people within Spokane and is likely to continue causing significant harm to patients with chronic  
24 pain who are being prescribed and take opioids, their families, and their communities.

25           439. But for Defendants’ actions, opioid use and ultimately its misuse and abuse would  
26 not be as widespread as it is today, and the massive epidemic of opioid abuse that currently exists  
27 would have been averted.

1           440. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair  
2 and deceptive conduct has caused the damage and harm complained of herein. Manufacturing  
3 Defendants knew or reasonably should have known that their statements regarding the risks and  
4 benefits of opioids were false and misleading, and that their false and misleading statements  
5 were causing harm from their continued production and marketing of opioids. Distributor  
6 Defendants knew that the widespread distribution of opioids would endanger the health and  
7 safety of residents of Spokane. Thus, the public nuisance caused by Defendants to Spokane was  
8 reasonably foreseeable, including the financial and economic losses incurred by the City.

9           441. Furthermore, Spokane brings this cause of action in its sovereign capacity for the  
10 benefit of the State of Washington. The applicable RCW with respect to a public nuisance  
11 expressly prohibits the conduct complained of herein, and this action is brought to promote the  
12 public welfare of the state and for the common good of the state.

13           442. In addition, engaging in any business in defiance of a law regulating or  
14 prohibiting the same is a nuisance per se under Washington law. Each Defendant's conduct  
15 described herein of deceptively marketing or excessively distributing opioids violates RCW  
16 7.48.010 and therefore constitutes a nuisance per se.

17           443. As a direct and proximate cause of Defendants' conduct creating or assisting in  
18 the creation of a public nuisance, Spokane, its community, and its residents have sustained and  
19 will continue to sustain substantial injuries.

20           444. Pursuant to RCW 7.48.020, Spokane requests an order providing for abatement of  
21 the public nuisance that each Defendant has created or assisted in the creation of, and enjoining  
22 Defendants from future violations of RCW 7.48.010.

23           445. Spokane also seeks the maximum statutory and civil penalties permitted by law as  
24 a result of the public nuisance created by Defendants.

### 25                                   **COUNT THREE — NEGLIGENCE**

26           446. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
27 fully set forth herein.

1           447. Under Washington law, a cause of action arises for negligence when a defendant  
2 owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury.  
3 *Iwai v. State*, 129 Wn. 2d 84, 96, 915 P.2d 1089 (1996).

4           448. Each Defendant owed a duty of care to Spokane, including but not limited to  
5 taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

6           449. In violation of this duty, Defendants failed to take reasonable steps to prevent the  
7 misuse, abuse, and over-prescription of opioids in Spokane by misrepresenting the risks and  
8 benefits associated with opioids and by distributing dangerous quantities of opioids.

9           450. As set forth above, Manufacturing Defendants' misrepresentations include falsely  
10 claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that  
11 prescribing more opioids was appropriate when patients presented symptoms of addiction,  
12 falsely claiming that risk-mitigation strategies could safely address concerns about addiction,  
13 falsely claiming that doctors and patients could increase opioid doses indefinitely without added  
14 risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and  
15 addiction, and falsely claiming that long-term opioid use could actually restore function and  
16 improve a patient's quality of life. Each of these misrepresentations made by Defendants violated  
17 the duty of care to Spokane.

18           451. Distributor Defendants negligently distributed enormous quantities of potent  
19 narcotics and failed to report such distributions. Distributor Defendants violated their duty of  
20 care by moving these dangerous products into Spokane in such quantities, facilitating diversion,  
21 misuse, and abuse of opioids.

22           452. As a direct and proximate cause of Defendants' unreasonable and negligent  
23 conduct, Plaintiff has suffered and will continue to suffer harm, and is entitled to damages in an  
24 amount determined at trial.

#### 25                           **COUNT FOUR — GROSS NEGLIGENCE**

26           453. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
27 fully set forth herein.



1           454. As set forth above, each Defendant owed a duty of care to Spokane, including but  
2 not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of  
3 opioids.

4           455. In violation of this duty, each Defendant failed to take reasonable steps to prevent  
5 the misuse, abuse, and over-prescription of opioids in Spokane by misrepresenting the risks and  
6 benefits associated with opioids.

7           456. In addition, each Defendant knew or should have known, and/or recklessly  
8 disregarded, that the opioids they manufactured, promoted, and distributed were being used for  
9 unintended uses.

10           457. For instance, Defendants failed to exercise slight care to Spokane by, *inter alia*,  
11 failing to take appropriate action to stop opioids from being used for unintended purposes.  
12 Furthermore, despite each Defendant's actual or constructive knowledge of the wide  
13 proliferation of prescription opioids in Spokane, Defendants took no action to prevent the abuse  
14 and diversion of these drugs. In fact, Manufacturing Defendants promoted and actively targeted  
15 doctors and their patients through training their sales representatives to encourage doctors to  
16 prescribe more opioids.

17           458. Manufacturing Defendants' misrepresentations include falsely claiming that the  
18 risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more  
19 opioids was appropriate when patients presented symptoms of addiction, falsely claiming that  
20 risk-mitigation strategies could safely address concerns about addiction, falsely claiming that  
21 doctors and patients could increase opioid doses indefinitely without added risk, deceptively  
22 marketing that purported abuse-deterrent technology could curb misuse and addiction, and  
23 falsely claiming that long-term opioid use could actually restore function and improve a patient's  
24 quality of life. Each of these misrepresentations made by Manufacturing Defendants violated the  
25 duty of care to Spokane, in a manner that is substantially and appreciably greater than ordinary  
26 negligence.

1           459. Distributor Defendants continued to funnel enormous quantities of opioids into  
2           Spokane, long after they knew that these products were being misused, abused, and diverted. By  
3           permitting the movement of such excessive quantities of dangerous narcotics into Spokane,  
4           Distributor Defendants endangered the health and safety of Spokane residents, in a manner that  
5           is substantially and appreciably greater than ordinary negligence.

6           460. As a direct and proximate cause of each Defendant's gross negligence, Spokane  
7           has suffered and will continue to suffer harm, and is entitled to damages in an amount  
8           determined at trial.

9                           **COUNT FIVE — UNJUST ENRICHMENT**

10          461. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
11          fully set forth herein.

12          462. Each Defendant was required to take reasonable steps to prevent the misuse,  
13          abuse, and over-prescription of opioids.

14          463. Rather than prevent or mitigate the wide proliferation of opioids into Spokane,  
15          each Defendant instead chose to place its monetary interests first, and each Defendant profited  
16          from prescription opioids sold in Spokane.

17          464. Each Defendant also failed to maintain effective controls against the unintended  
18          and illegal use of the prescription opioids it manufactured or distributed, again choosing instead  
19          to place its monetary interests first.

20          465. Each Defendant therefore received a benefit from the sale and distribution of  
21          prescription opioids to and in Spokane, and these Defendants have been unjustly enriched at the  
22          expense of Spokane.

23          466. As a result, Spokane is entitled to damages on its unjust enrichment claim in an  
24          amount to be proven at trial.

**COUNT SIX — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (“RICO”), 18 U.S.C. § 1961, *ET SEQ.***

467. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

468. This claim is brought by Plaintiff against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et seq.*

469. At all relevant times, each Defendant is and has been a “person” within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, “a legal or beneficial interest in property.”

470. Plaintiff is a “person,” as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of the Defendants’ wrongful conduct described herein.

471. Section 1962(c) makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity . . .” 18 U.S.C. § 1962(c).

472. Section 1962(d) makes it unlawful for “any person to conspire to violate” Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

473. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

**A. Description of the Defendants’ Enterprises.**

474. RICO defines an enterprise as “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4).

475. Under 18 U.S.C. § 1961(4) a RICO “enterprise” may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among

1 those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's  
2 purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

3 476. Defendants formed two such association-in-fact enterprises—referred to herein as  
4 “the Opioid Marketing Enterprise” and “the Opioid Supply Chain Enterprise.”

5 477. The Opioid Marketing Enterprise consists of Defendants Endo, Janssen, Teva,  
6 Actavis, and Mallinckrodt, Front Groups, and KOLs. In particular, the Opioid Marketing  
7 Enterprise consists of (a) Defendant Endo, including its employees and agents, (b) Defendant  
8 Janssen, including its employees and agents, (c) Defendant Teva, including its employees and  
9 agents, (d) Defendant Actavis, including its employees and agents, and (e) Defendant  
10 Mallinckrodt, including its employees and agents (collectively, “Marketing Defendants”); certain  
11 front groups described above, including but not limited to (a) the American Pain Foundation,  
12 including its employees and agents, (b) the American Academy of Pain Medicine, including its  
13 employees and agents, and (c) the American Pain Society, including its employees and agents  
14 (collectively, the “Front Groups”); and certain Key Opinion Leaders, including but not limited to  
15 (a) Dr. Russell Portenoy, (b) Dr. Perry Fine, (c) Dr. Lynn Webster, and (d) Dr. Scott Fishman  
16 (collectively, the “KOLs”). The entities in the Opioid Marketing Enterprise acted in concert to  
17 create demand for prescription opioids.

18 478. Alternatively, each of the above-named Marketing Defendants and Front Groups  
19 constitutes a single legal entity “enterprise” within the meaning of 18 U.S.C. § 1961(4), through  
20 which the members of the enterprise conducted a pattern of racketeering activity. The separate  
21 legal status of each member of the Enterprise facilitated the fraudulent scheme and provided a  
22 hoped-for shield from liability for Defendants and their co-conspirators.

23 479. Alternatively, each of the Marketing Defendants, together with the Distributor  
24 Defendants, the Front Groups, and the KOLs, constitute separate, associated-in-fact Enterprises  
25 within the meaning of 18 U.S.C. § 1961(4).

26 480. The Opioid Supply Chain Enterprise consists of all Defendants. In particular, the  
27 Opioid Supply Chain Enterprise consists of (a) Defendant Endo, including its employees and

1 agents, (b) Defendant Janssen, including its employees and agents, (c) Defendant Teva, including  
2 its employees and agents, (d) Defendant Actavis, including its employees and agents, (e)  
3 Defendant Mallinckrodt, including its employees and agents, (f) Defendant AmerisourceBergen,  
4 including its employees and agents, (g) Defendant Cardinal Health, including its employees and  
5 agents, and (h) Defendant McKesson, including its employees and agents (collectively,  
6 “Defendants”).

7 481. The CSA and its implementing regulations require all manufacturers and  
8 distributors of controlled substances, including opioids, to maintain a system to identify and  
9 report suspicious orders, including orders of unusual size or frequency, or orders deviating from  
10 a normal pattern, and maintain effective controls against diversion of controlled substances. *See*  
11 21 U.S.C. § 823; 21 C.F.R. §1301.74(b). All Defendants—manufacturers and distributors  
12 alike—are required to become “registrants” under the CSA, 21 U.S.C. § 823(a)-(b), and its  
13 implementing regulations, which provide that “[e]very person who manufactures, distributes,  
14 dispenses, imports, or exports any controlled substance. . . shall obtain a registration[.]” 21  
15 C.F.R. § 1301.11(a). Defendants’ duties as registrants include reporting suspicious orders of  
16 controlled substances, which are defined as including “orders of unusual size, orders deviating  
17 substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

18 482. The Manufacturing Defendants carried out the Opioid Supply Chain Enterprise by  
19 incentivizing and supplying suspicious sales of opioids, despite their knowledge that their  
20 opioids were being diverted to illicit use, and by failing to notify the DEA of such suspicious  
21 orders as required by law. The Distributor Defendants carried out the Opioid Supply Chain  
22 Enterprise by failing to maintain effective controls against diversion, intentionally evading their  
23 obligation to report suspicious orders to the DEA, and conspiring to prevent limits on the  
24 prescription opioids they were oversupplying to communities like Plaintiff.

25 483. The Opioid Marketing Enterprise is an ongoing and continuing business  
26 organization consisting of “persons” within the meaning of 18 U.S.C. § 1961(3) that created and  
27 maintained systematic links for a common purpose: to sell highly addictive opioids for treatment

1 of chronic pain while knowing that opioids have little or no demonstrated efficacy for such pain  
2 and have significant risk of addiction, overdose, and death.

3 484. The Opioid Supply Chain Enterprise is an ongoing and continuing business  
4 organization consisting of “persons” within the meaning of 18 U.S.C. § 1961(3) that created and  
5 maintained systematic links for a common purpose: to distribute highly addictive opioids in  
6 quantities that far exceeded amounts that could reasonably be considered medically necessary.

7 485. To accomplish these purposes, the Opioid Marketing Enterprise engaged in a  
8 sophisticated, well-developed, and fraudulent marketing scheme designed to increase the  
9 prescription rate for Defendants’ opioid medications (the “Marketing Scheme”), and the Opioid  
10 Supply Chain Enterprise carried out a scheme to systematically disregard, avoid, or frustrate the  
11 monitoring and reporting requirements intended to prevent the widespread distribution of  
12 dangerous controlled substances (the “Diversion Scheme”). The Marketing Scheme and the  
13 Diversion Scheme are collectively referred to as the “Schemes.” Together, Defendants engaged  
14 in these broad Schemes with the overarching purposes of materially expanding prescription  
15 opioid use by altering the medical community’s opioid prescribing practices through repeated  
16 fraudulent statements and misrepresentations and materially expanding prescription opioid  
17 supply by avoiding monitoring requirements and actively seeking higher quotas.

18 **B. The Enterprises Sought to Fraudulently Increase Defendants’ Profits and Revenues**

19 486. At all relevant times, each Defendant was aware of the conduct of the Enterprises,  
20 was a knowing and willing participant in that conduct, and reaped profits from that conduct in  
21 the form of increased sales and distribution of prescription opioids. In addition, the Front Groups  
22 and KOLs received direct payments from the Marketing Defendants in exchange for their role in  
23 the Opioid Marketing Enterprise, and to advance the Opioid Marketing Enterprise’s fraudulent  
24 marketing scheme.

25 487. The Enterprises engaged in, and their activities affected, interstate and foreign  
26 commerce because they involved commercial activities across state boundaries, including but not  
27 limited to: (1) the marketing, promotion, and distribution of prescription opioids; (2) advocacy at

1 the state and federal level for change in the law governing the use and prescription of  
2 prescription opioids; (3) the issuance of prescriptions and prescription guidelines for opioids; (4)  
3 the issuance of fees, bills, and statements demanding payment for prescriptions of opioids; (5)  
4 payments, rebates, and chargebacks between Defendants; and (6) the creation of documents,  
5 reports, and communications related to Defendants' reporting requirements under the CSA and  
6 its implementing regulations.

7 488. The persons engaged in the Enterprises are systematically linked through  
8 contractual relationships, financial ties, and continuing coordination of activities, as spearheaded  
9 by Defendants. With respect to the Opioid Marketing Enterprise, each Marketing Defendant  
10 funded and directed the operations of the KOLs and the Front Groups; in fact, the board of  
11 directors of each of the Front Groups are and were full of doctors who were on the Marketing  
12 Defendants' payrolls, either as consultants or speakers at medical events. Moreover, each  
13 Marketing Defendant coordinated and, at times, co-funded their activities in furtherance of the  
14 goals of the Enterprise. This coordination can also be inferred through the consistent  
15 misrepresentations described below. With respect to the Opioid Supply Chain Enterprise,  
16 Defendants were financially linked through a system of payments, rebates, and chargebacks.

17 489. In the Opioid Marketing Enterprise, there is regular communication between each  
18 Marketing Defendant, each of the Front Groups, and each KOL in which information regarding  
19 the Defendants' scheme to increase opioid prescriptions is shared. Typically, this communication  
20 occurred, and continues to occur, through the use of the wires and the mail in which Marketing  
21 Defendants, the Front Groups, and the KOL share information regarding the operation of the  
22 Opioid Marketing Enterprise.

23 490. In the Opioid Supply Chain Enterprise, there is regular communication between  
24 each Defendant in which information regarding the Defendants' scheme to oversupply opioids  
25 and avoid restrictive regulations or quotas is shared. Typically, this communication occurred,  
26 and continues to occur, through the use of the wires and the mail in which Defendants share  
27 information regarding the operation of the Opioid Supply Chain Enterprise.



1           491. The Enterprises functioned as continuing units for the purposes of executing the  
2 Schemes, and when issues arose during the Schemes, each member of the Enterprises agreed to  
3 take actions to hide the Schemes and the existence of the Enterprises.

4           492. Each Defendant participated in the operation and management of the Enterprises  
5 by directing its affairs as described herein.

6           493. While Defendants participate in, and are members of, the Enterprises, they have  
7 an existence separate from the Enterprises, including distinct legal statuses, affairs, offices and  
8 roles, officers, directors, employees, and individual personhood.

9           494. Each Marketing Defendant orchestrated the affairs of the Opioid Marketing  
10 Enterprise and exerted substantial control over the Opioid Marketing Enterprise by, at least: (1)  
11 making misleading statements about the purported benefits, efficacy, and risks of opioids to  
12 doctors, patients, the public, and others, in the form of telephonic and electronic  
13 communications, CME programs, medical journals, advertisements, and websites; (2) employing  
14 sales representatives to promote the use of opioid medications; (3) purchasing and utilizing  
15 sophisticated marketing data (e.g., IMS data) to coordinate and refine the Marketing Scheme; (4)  
16 employing doctors to serve as speakers at or attend all-expense paid trips to programs  
17 emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and  
18 operating the Front Groups, including the American Pain Foundation and the Pain & Policy  
19 Studies Group; (6) sponsoring CME programs that claimed that opioid therapy has been shown  
20 to reduce pain and depressive symptoms; (7) supporting and sponsoring guidelines indicating  
21 that opioid medications are effective and can restore patients' quality of life; (8) retaining KOLs  
22 to promote the use of opioids; and (9) concealing the true nature of their relationships with the  
23 other members of the Marketing Scheme, and the Opioid Marketing Enterprise, including the  
24 Front Groups and the KOLs.

25           495. The Front Groups orchestrated the affairs of the Opioid Marketing Enterprise and  
26 exerted substantial control over the Opioid Marketing Enterprise by, at least: (1) making  
27 misleading statements about the purported benefits, efficacy, and low risks of opioids described

1 herein; (2) holding themselves out as independent advocacy groups, when in fact their operating  
2 budgets are entirely comprised of contributions from opioid drug manufacturers; (3) publishing  
3 treatment guidelines that advised the prescription of opioids; (4) sponsoring medical education  
4 programs that touted the benefits of opioids to treat chronic pain while minimizing and  
5 trivializing their risks; and (5) concealing the true nature of their relationship with the other  
6 members of the Opioid Marketing Enterprise.

7 496. The KOLs orchestrated the affairs of the Opioid Marketing Enterprise and exerted  
8 substantial control over the Opioid Marketing Enterprise by, at least: (1) making misleading  
9 statements about the purported benefits, efficacy, and low risks of opioids; (2) holding  
10 themselves out as independent, when in fact they are systematically linked to and funded by  
11 opioid drug manufacturers; and (3) concealing the true nature of their relationship with the other  
12 members of the Opioid Marketing Enterprise.

13 497. Without the willing participation of each member of the Opioid Marketing  
14 Enterprise, the Marketing Scheme and the Opioid Marketing Enterprise's common course of  
15 conduct would not have been successful.

16 498. Each Distributor Defendant orchestrated the affairs of the Opioid Supply Chain  
17 Enterprise and exerted substantial control over the Opioid Supply Chain Enterprise by, at least:  
18 (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA;  
19 (2) providing the Manufacturing Defendants with data regarding their prescription opioid sales,  
20 including purchase orders and ship notices; (3) accepting payments from the Manufacturing  
21 Defendants in the form of rebates and/or chargebacks; (4) filling suspicious orders for  
22 prescription opioids despite having identified them as suspicious and knowing opioids were  
23 being diverted into the illicit drug market; (5) working with other members of the Enterprise  
24 through groups like the Healthcare Distribution Alliance and the Pain Care Forum to ensure the  
25 free flow of opioids, including by supporting limits on the DEA's ability to use immediate  
26 suspension orders; and (6) concealing the true nature of their relationships with the other  
27 members of the Opioid Supply Chain Enterprise.

1           499. Each Manufacturing Defendant orchestrated the affairs of the Opioid Supply  
2 Chain Enterprise and exerted substantial control over the Opioid Supply Chain Enterprise by, at  
3 least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the  
4 DEA; (2) obtaining from the Distributor Defendants data regarding their prescription opioid  
5 sales, including purchase orders and ship notices; (3) providing payments to the Distributor  
6 Defendants in the form of rebates and/or chargebacks; (4) working with other members of the  
7 Opioid Supply Chain Enterprise through groups like the Healthcare Distribution Alliance to  
8 ensure the free flow of opioids, including by supporting limits on the DEA's ability to use  
9 immediate suspension orders; and (5) concealing the true nature of their relationships with the  
10 other members of the Opioid Supply Chain Enterprise.

11           500. Without the willing participation of each member of the Opioid Supply Chain  
12 Enterprise, the Diversion Scheme and the Opioid Supply Chain Enterprise's common course of  
13 conduct would not have been successful.

14 **C. Predicate Acts: Mail and Wire Fraud**

15           501. To carry out, or attempt to carry out, the Schemes, the members of the  
16 Enterprises, each of whom is a person associated-in-fact with the Enterprises, did knowingly  
17 conduct or participate in, directly or indirectly, the affairs of the Enterprises through a pattern of  
18 racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and  
19 employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud)  
20 and § 1343 (wire fraud).

21           502. Specifically, the members of the Enterprises have committed, conspired to  
22 commit, and/or aided and abetted in the commission of, at least two predicate acts of  
23 racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

24           503. The multiple acts of racketeering activity which the members of the Enterprises  
25 committed, or aided or abetted in the commission of, were related to each other, posed a threat of  
26 continued racketeering activity, and therefore constitute a "pattern of racketeering activity."  
27

1           504. The racketeering activity was made possible by the Enterprises' regular use of the  
2 facilities, services, distribution channels, and employees of the Enterprises.

3           505. The members of the Enterprises participated in the Schemes by using mail,  
4 telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

5           506. The members of the Enterprises used, directed the use of, and/or caused to be  
6 used, thousands of interstate mail and wire communications in service of their Schemes through  
7 common misrepresentations, concealments, and material omissions.

8           507. In devising and executing the illegal Schemes, the members of the Enterprises  
9 devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the  
10 public to obtain money by means of materially false or fraudulent pretenses, representations,  
11 promises, or omissions of material facts.

12           508. For the purpose of executing the illegal Schemes, the members of the Enterprises  
13 committed these racketeering acts, which number in the thousands, intentionally and knowingly  
14 with the specific intent to advance the illegal Schemes.

15           509. The Enterprises' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but  
16 are not limited to:

17           A. Mail Fraud: The members of the Enterprises violated 18 U.S.C. § 1341 by  
18 sending or receiving, or by causing to be sent and/or received, fraudulent materials  
19 via U.S. mail or commercial interstate carriers for the purpose of selling and  
distributing excessive quantities of highly addictive opioids.

20           B. Wire Fraud: The members of the Enterprises violated 18 U.S.C. § 1343 by  
21 transmitting and/or receiving, or by causing to be transmitted and/or received,  
22 fraudulent materials by wire for the purpose of selling and distributing excessive  
quantities of highly addictive opioids.

23           510. The Marketing Defendants falsely and misleadingly used the mails and wires in  
24 violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the  
25 following: Purdue's (1) May 31, 1996 press release announcing the release of OxyContin and  
26 indicating that the fear of OxyContin's addictive properties was exaggerated; (2) 1990  
27 promotional video in which Dr. Portenoy, a paid Purdue KOL, understated the risk of opioid

1 addiction; (3) 1998 promotional video which misleadingly cited a 1980 NEJM letter in support  
2 of the use of opioids to treat chronic pain; (4) statements made on its 2000 “Partners Against  
3 Pain” website which claimed that the addiction risk of OxyContin was very low; (5) literature  
4 distributed to physicians which misleadingly cited a 1980 NEJM letter in support of the use of  
5 opioids to treat chronic pain; (6) August 2001 statements to Congress by Purdue Executive Vice  
6 President and Chief Operating Officer Michael Friedman regarding the value of OxyContin in  
7 treating chronic pain; (7) patient brochure entitled “A Guide to Your New Pain Medicine and  
8 How to Become a Partner Against Pain” indicating that OxyContin is non-addicting; (8) 2001  
9 statement by Senior Medical Director for Purdue, Dr. David Haddox, indicating that the  
10 ‘legitimate’ use of OxyContin would not result in addiction; (9) multiple sales representatives’  
11 communications regarding the low risk of addiction associated with opioids; (10) statements  
12 included in promotional materials for opioids distributed to doctors via the mail and wires; (11)  
13 statements in a 2003 Patient Information Guide distributed by Purdue indicating that addiction to  
14 opioid analgesics in properly managed patients with pain has been reported to be rare; (12)  
15 telephonic and electronic communications to doctors and patients indicating that signs of  
16 addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements  
17 in Purdue’s Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking  
18 behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior; (14)  
19 statements made on Purdue’s website and in a 2010 “Dear Healthcare Professional” letter  
20 indicating that opioid dependence can be addressed by dosing methods such as tapering; (15)  
21 statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for  
22 opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent  
23 opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin  
24 indicating that long-term opioid use improves patients’ function and quality of life; (18)  
25 statements made in advertising and a 2007 book indicating that pain relief from opioids improve  
26 patients’ function and quality of life; (19) telephonic and electronic communications by its sales  
27 representatives indicating that opioids will improve patients’ function; and (20) electronic and

1 telephonic communications concealing its relationship with the other members of the  
2 Enterprises.

3         511. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in  
4 violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made,  
5 beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that  
6 patients who take opioids as prescribed usually do not become addicted; (2) statements made on  
7 another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do  
8 not become addicted to opioid medications; (3) statements in pamphlets and publications  
9 described by Endo indicating that most people who take opioids for pain relief do not develop an  
10 addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use  
11 does not result in addiction; (5) statements made on the Endo-run website, Opana.com,  
12 indicating that opioid dependence can be addressed by dosing methods such as tapering; (6)  
13 statements made on its website, PainKnowledge.com, that opioid dosages could be increased  
14 indefinitely; (7) statements made in a publication entitled “Understanding Your Pain: Taking  
15 Oral Opioid Analgesics” suggesting that opioid doses can be increased indefinitely; (8)  
16 electronic and telephonic communications to its sales representatives indicating that the formula  
17 for its medicines is ‘crush resistant;’ (9) statements made in advertisements and a 2007 book  
18 indicating that pain relief from opioids improves patients’ function and quality of life; (10)  
19 telephonic and electronic communications by its sales representatives indicating that opioids will  
20 improve patients’ function; and (11) telephonic and electronic communications concealing its  
21 relationship with the other members of the Enterprises.

22         512. Defendant Janssen made false or misleading claims in violation of 18 U.S.C. §  
23 1341 and § 1343 including but not limited to: (1) statements on its website,  
24 PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated; (2)  
25 statements in a 2009 patient education guide claiming that opioids are rarely addictive when used  
26 properly; (3) statements included on a 2009 Janssen-sponsored website promoting the concept of  
27 opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, advocating the

1 concept of opioid pseudoaddiction; (5) statements on its website, PrescribeResponsibly.com,  
2 indicating that opioid addiction can be managed; (6) statements in its 2009 patient education  
3 guide indicating the risks associated with limiting the dosages of pain medicines; (7) telephonic  
4 and electronic communications by its sales representatives indicating that opioids will improve  
5 patients' function; and (8) telephonic and electronic communications concealing its relationship  
6 with the other members of the Enterprises.

7 513. The American Academy of Pain Medicine made false or misleading claims in  
8 violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a  
9 2009 patient education video entitled "Finding Relief: Pain Management for Older Adults"  
10 indicating the opioids are rarely addictive; and (2) telephonic and electronic communications  
11 concealing its relationship with the other members of the Opioid Marketing Enterprise.

12 514. The American Pain Society Quality of Care Committee made a number of false or  
13 misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a  
14 May 31, 1996 press release in which the organization claimed there is very little risk of addiction  
15 from the proper use of drugs for pain relief; and (2) telephonic and electronic communications  
16 concealing its relationship with the other members of the Opioid Marketing Enterprise.

17 515. The American Pain Foundation ("APF") made a number of false and misleading  
18 claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements  
19 made by an APF Executive Director to Congress indicating that opioids only rarely lead to  
20 addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court  
21 claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment  
22 of chronic pain; (3) statements made in a 2007 publication entitled "Treatment Options: A Guide  
23 for People Living with Pain" indicating that the risks of addiction associated with opioid  
24 prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that  
25 opioid users are not "actual addicts;" (5) statements made in a 2007 publication entitled  
26 "Treatment Options: A Guide for People Living with Pain" indicating that even physical  
27 dependence on opioids does not constitute addiction; (6) claims on its website that there is no



1 ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that  
2 opioids can improve daily function; and (8) telephonic and electronic communications  
3 concealing its relationship with the other members of the Opioid Marketing Enterprise.

4 516. The KOLs, including Drs. Russell Portenoy, Perry Fine, Scott Fishman, and Lynn  
5 Webster, made a number of misleading statements in the mail and wires in violation of 18 U.S.C.  
6 § 1341 and § 1343, described above, including statements made by Dr. Portenoy in a  
7 promotional video indicating that the likelihood of addiction to opioid medications is extremely  
8 low. Indeed, Dr. Portenoy has since admitted that his statements about the safety and efficacy of  
9 opioids were false.

10 517. The Manufacturing Defendants and Distributor Defendants falsely and  
11 misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative  
12 and non-exhaustive examples include the following: (1) the transmission of documents and  
13 communications regarding the sale, shipment, and delivery of excessive quantities of  
14 prescription opioids, including invoices and shipping records; (2) the transmission of documents  
15 and communications regarding their requests for higher aggregate production quotas, individual  
16 manufacturing quotas, and procurement quotas; (3) the transmission of reports to the DEA that  
17 did not disclose suspicious orders as required by law; (4) the transmission of documents and  
18 communications regarding payments, rebates, and chargebacks; (5) the transmission of the actual  
19 payments, rebates, and chargebacks themselves; (6) correspondence between Defendants and  
20 their representatives in front groups and trade organizations regarding efforts to curtail  
21 restrictions on opioids and hobble DEA enforcement actions; (7) the submission of false and  
22 misleading certifications required annually under various agreements between Defendants and  
23 federal regulators; and (8) the shipment of vast quantities of highly addictive opioids. Defendants  
24 also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail and  
25 with various other affiliates, regional offices, regulators, distributors, and other third-party  
26 entities in furtherance of the scheme.

1           518. In addition, the Distributor Defendants misrepresented their compliance with laws  
2 requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or  
3 diversion into the illicit market. At the same time, the Distributor Defendants misrepresented the  
4 effectiveness of their monitoring programs, their ability to detect suspicious orders, their  
5 commitment to preventing diversion of prescription opioids, and their compliance with  
6 regulations regarding the identification and reporting of suspicious orders of prescription opioids.

7           519. The mail and wire transmissions described herein were made in furtherance of  
8 Defendants' Schemes and common course of conduct designed to sell drugs that have little or no  
9 demonstrated efficacy for the pain they are purported to treat in the majority of persons  
10 prescribed them; increase the prescription rate for opioid medications; and popularize the  
11 misunderstanding that the risk of addiction to prescription opioids is low when used to treat  
12 chronic pain, and to deceive regulators and the public regarding Defendants' compliance with  
13 their obligations to identify and report suspicious orders of prescription opioids, while  
14 Defendants intentionally enabled millions of prescription opioids to be deposited into  
15 communities across the United States, including in Spokane. Defendants' scheme and common  
16 course of conduct was intended to increase or maintain high quotas for the manufacture and  
17 distribution of prescription opioids and their corresponding high profits for all Defendants.

18           520. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate  
19 wire facilities have been deliberately hidden and cannot be alleged without access to Defendants'  
20 books and records. However, Plaintiff has described the types of predicate acts of mail and/or  
21 wire fraud, including certain specific fraudulent statements and specific dates upon which,  
22 through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the  
23 Schemes.

24           521. The members of the Enterprises have not undertaken the practices described  
25 herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §  
26 1962(d), the members of the Enterprises conspired to violate 18 U.S.C. § 1962(c), as described  
27 herein. Various other persons, firms, and corporations, including third-party entities and

1 individuals not named as defendants in this Complaint, have participated as co-conspirators with  
2 Defendants and the members of the Enterprises in these offenses and have performed acts in  
3 furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or  
4 minimize losses for the Defendants and their named and unnamed co-conspirators throughout the  
5 illegal scheme and common course of conduct.

6 522. The members of the Enterprises aided and abetted others in the violations of the  
7 above laws.

8 523. To achieve their common goals, the members of the Enterprises hid from Plaintiff  
9 and the public: (1) the fraudulent nature of the Marketing Defendants' marketing scheme; (2) the  
10 fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the  
11 efficacy of and risk of addiction associated with prescription opioids; (3) the fraudulent nature of  
12 the Distributor Defendants' representations regarding their compliance with requirements to  
13 maintain effective controls against diversion and report suspicious orders of opioids; and (4) the  
14 true nature of the relationship between the members of the Enterprises.

15 524. Defendants and each member of the Enterprises, with knowledge and intent,  
16 agreed to the overall objectives of the Schemes and participated in the common course of  
17 conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprises and their  
18 co-conspirators had to agree to conceal their fraudulent scheme.

19 525. The members of the Enterprises knew, and intended that, Plaintiff and the public  
20 would rely on the material misrepresentations and omissions made by them and suffer damages  
21 as a result.

22 526. As described herein, the members of the Enterprises engaged in a pattern of  
23 related and continuous predicate acts for years. The predicate acts constituted a variety of  
24 unlawful activities, each conducted with the common purpose of obtaining significant monies  
25 and revenues from Plaintiff and the public based on their misrepresentations and omissions.

26 527. The predicate acts also had the same or similar results, participants, victims, and  
27 methods of commission.

1           528. The predicate acts were related and not isolated events.

2           529. The true purposes of Defendants' Schemes were necessarily revealed to each  
3 member of the Enterprises. Nevertheless, the members of the Enterprises continued to  
4 disseminate misrepresentations regarding the nature of prescription opioids and the functioning  
5 of the Schemes.

6           530. Defendants' fraudulent concealment was material to Plaintiff and the public. Had  
7 the members of the Enterprises disclosed the true nature of prescription opioids and their  
8 excessive distribution, Plaintiff would not have acted as it did or incurred the substantial costs in  
9 responding to the crisis caused by Defendants' conduct.

10          531. The pattern of racketeering activity described above is currently ongoing and  
11 open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering  
12 activity.

13 **D. Spokane Has Been Damaged by Defendants' RICO Violations**

14          532. By reason of, and as a result of the conduct of the Enterprises and, in particular,  
15 their patterns of racketeering activity, Spokane has been injured in its business and/or property in  
16 multiple ways, including but not limited to increased health care costs, increased human services  
17 costs, costs related to dealing with opioid-related crimes and emergencies, and other public  
18 safety costs, as fully described above. The City will continue incurring these substantial costs  
19 well into the future. The Marketing Defendants' deceptive marketing scheme changed the way  
20 physicians prescribe opioids, and together with their systemic undermining of quotas and  
21 institutional controls as well as the failure to report suspicious orders by both the Manufacturing  
22 and Distributor Defendants, Defendants achieved an enormous increase in the number of opioids  
23 sold and distributed across the country and in Spokane.

24          533. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and  
25 proximately caused injuries and damages to Spokane, its community, and the public, and the  
26 City is entitled to bring this action for three times its actual damages, as well as  
27 injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff City of Spokane respectfully requests the Court order the following relief:

- A. An Order that the conduct alleged herein violates the Washington CPA;
- B. An Order that Plaintiff is entitled to treble damages pursuant to the Washington CPA;
- C. An Order that the conduct alleged herein constitutes a public nuisance, including under RCW 7.48 *et seq.* and under Washington law;
- D. An Order that Defendants abate the public nuisance that they caused;
- E. An Order that Defendants are liable for civil and statutory penalties to the fullest extent permissible under Washington law for the public nuisance they caused;
- F. An Order that Defendants are negligent under Washington law;
- G. An Order that Defendants are grossly negligent under Washington law;
- H. An Order that Defendants have been unjustly enriched at Plaintiff's expense under Washington law;
- I. An Order that Defendants' conduct constitutes violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*;
- J. An Order that Plaintiff is entitled to recover all measure of damages permissible under the statutes identified herein and under common law;
- K. An Order that Defendants are enjoined from the practices described herein;
- L. An Order that judgment be entered against Defendants in favor of Plaintiff;
- M. An Order that Plaintiff is entitled to attorneys' fees and costs pursuant to any applicable provision of law, including but not limited to under the Washington CPA; and
- N. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

**JURY TRIAL DEMAND**

Plaintiff demands a trial by jury on all claims and of all issues so triable.

DATED this 4th day of November, 2019.

**CITY OF SPOKANE**

**KELLER ROHRBACK L.L.P.**

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